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Kauffman

ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

X Synes (cont'd)

Labrow

The Honourable Mr. Justice S.G.M. Grange

Commissioner

P.S.A. Lamek, Q.C.

Counsel

E.A. Cronk

Associate Counsel

Thomas Millar

Administrator

Tobias

Transcript of evidence
for

December 19, 1983

Jachman

VOLUME 83

Ceschells

Re: "LEAC"

OFFICIAL COURT REPORTERS

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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN
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Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Monday, the 19th
day of December, 1983.

- - - - -

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

- - - - -

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K. CHOWN	Counsel for numerous Doctors at The Hospital for Sick Children
B. SYMES	Counsel for the Registered Nurses' Association of Ontario and 35 Registered Nurses at The Hospital for Sick Children

(Cont'd)



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1 APPEARANCES: (Continued)

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& Mrs. Lutes, and Mr. & Mrs.
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children)
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14 F.J. SHANAHAN Counsel for Mr. & Mrs. Dominic
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Heather Dawson (mother of
deceased child Amber Dawson)
15
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18 W.W. TOBIAS Counsel for Mr. & Mrs. Hines
(parents of deceased child
Jordan Hines)
19
20
21
22
23
24
25



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A/BM/ak

1
2 ---Upon commencing at 10:00 a.m.

3 THE COMMISSIONER: The stated case
4 is prepared. It isn't yet ready for release because
5 it is being checked by people more familiar with
6 stated cases than I am. I have a tentative date
7 for the 3rd of February. Now, that may not be
8 soon enough but I had decided upon reflection that
9 it was just a shade improper for me to be speaking
10 to any of the judges involved, so, I spoke to
11 Mr. Bridges and I also told the Chief Justice that
12 I was speaking to him. He has the 3rd of February
13 available; there may well be an earlier date though
14 coming along, we will just have to take whatever is
15 available and counsel will just have to make them-
16 selves available.

17 I would at least I would think close
18 down the shop here for the day and I hope it will
19 only be a day that it is going to take.

20 MR. LAMEK: It is a Friday anyway.

21 THE COMMISSIONER: Yes, it is a
22 Friday but if it becomes another day I will close
23 down for that day.

24 Now, Miss Symes.

25 DR. RALPH KAUFFMAN, Recalled



CROSS-EXAMINATION BY MS. SYMES: (Continued)

Q. Good morning, Dr. Kauffman.

A. Good morning.

Q. I want to just ask you about one topic and that is medication error, the possibility of medication error.

You talked about it I believe in your evidence in Volume 54 beginning at page 2134. It is Volume 54, page 2134, it is on October 24th, 1983.

THE COMMISSIONER: I'm sorry?

MS. SYMES: But that was Spielberg, Mr. Commissioner.

THE COMMISSIONER: All right.

MS. SYMES: Q. Spielberg is the one I'm going to refer to.

Dr. Kauffman, the hospital that you are at, does it have a unit dose system?

A. We have a form of a unit dose system. I suppose I could say yes in all intents and purposes we do.

Q. And how long have you had that system?

A. I'm not certain but I think it has been gradually instituted within the last two to three years.



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Q. And have you noticed that there has been a change in the level of drug errors or medication errors since the institution of that system?

6

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A. I haven't specifically looked at that. I have no data or haven't attempted to measure that and I have no data one way or the other on that issue in our hospital.

10

11

Q. All right. Dr. Spielberg in his evidence had said that at this Hospital - this is on page 2134.

12

13

14

A. I'm sorry, which page?

Q. 2134 of the volume.

A. Right.

15

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18

Q. That there are approximately between 10,000 and 15,000 doses of digoxin being administered on Wards 4A/4B in a year. That is apparently the approximate number of doses that we are dealing with in this particular case.

19

20

21

Dr. Kauffman, are you aware of the literature with respect to the error rate in non-unit dose hospitals?

22

23

24

25

A. I am aware in general; it has been a while since I have looked at that literature but I am aware in general that the error



1
2 rate with non-unit dose drug dispensing in hospitals
3 is associated with a higher rate of medication error
4 than with unit dose.

5 Q. We have heard somewhere
6 between 5.5 per cent and 20.6 per cent, does that
7 seem within the range?

8 A. I haven't read those papers
9 for a while but I think, if I remember correctly,
10 that those numbers include all sorts of errors,
11 the majority of which have no particular significance
12 in terms of causing ill effects to the patient.

13 Q. Oh, absolutely. I mean, that
14 is unfortunate.

15 A. Those kinds of numbers have
16 been reported, yes.

17 Q. And I presume you would agree
18 with me even in an institution such as yours that
19 drug errors do occur?

20 A. Oh, I think they occur in
21 every hospital, unfortunately.

22 Q. Would you agree with me that
23 they are in fact system or systemic errors?

24 A. I'm not sure I understand your
25 question.

Q. That they are not only



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because humans make errors but because of the particular complexities of the delivery of medications in a system such as a hospital?

5

6

7

A. Well, I think they are due to a number of causes, errors facilitated by a particular system could be one cause, it's not the only cause.

8

9

Q. Well, for example, there could be an error in drug ordering?

10

11

A. There may be.

Q. There could be errors in

transcribing the doctor's order?

12

A. That's a possibility.

13

14

Q. There could be errors in dispensing, that is, either the wrong drug or the wrong amount?

15

16

A. That's correct.

17

Q. There could be an error that is given to the wrong patient?

18

A. That is correct.

19

20

Q. There could be an error in recording?

21

22

A. You mean after the dose is given?

23

Q. Yes.

24

A. That's a possibility.

25



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Q. And there could be an error
in time?

4

A. Yes, that is a possibility.

5

6

7

Q. And all of these are possibilities within virtually any medication delivery system?

8

9

A. I think they are always possibilities.

10

11

Q. And would you agree with me that most errors, medication errors go unrecorded?

12

13

14

A. I don't know that I can either agree with you or disagree with you. I'm not sure I have a data on which to base a judgment to that statement.

15

16

Q. Would you agree with me that many medication errors simply aren't detected?

17

18

19

A. I suspect that that is the case but I don't know it as a fact. It wouldn't surprise me if somebody showed me data to that effect, but I don't have any.

20

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22

23

Q. But that would seem reasonable would it not, Dr. Kauffman, that unless someone is aware or actually catches in the medication error it would go unnoticed?

24

25

A. Well, obviously if nobody is



1
2 aware of the error it would go unnoticed, that is
3 correct.

4 Q. Now, the possibility of an
5 error in a particular case then, would you agree
6 with me that those are independent events, that is,
7 if you have two patients who were receiving medica-
8 tion that the probability of error in each is an
9 independent event?

10 A. I don't know that they are
11 totally independent. It is difficult to answer that
12 because I don't know to what degree in a given
13 system errors could be interdependent. I suspect
14 there is some independence but to what degree I
don't really know.

15 Q. Well, the interdependence
16 might be if the same system were in place and that
17 system were producing errors, is that what you are
talking about interdependence of errors?

18 A. Well, I think that there is
19 a possibility for interdependence with factors
20 producing errors; for example, if a system which
21 included a certain mechanism for transcribing an
22 order and a certain mechanism for getting the order
23 to the pharmacy and certain mechanism for the
24 pharmacist to dispense the medication to the floor
25



1
2
3 or the nurse to administer the medication, within
4 a system there could be some interdependence in
5 terms of producing errors but to what degree these
6 various potential causes of errors are totally
independent of each other I really don't know.

7 Q. Can you agree with me that
8 these errors can and in fact do repeat; in other
9 words, the same error can be made over and over
again?

10 A. Well, that is difficult to
11 answer. I think it is unlikely if an error is
12 frequently repeated that it will not be picked up
13 and an intervention instituted.

14 Q. Well, I understand about
15 intervention but do you agree with me that sometimes
16 errors do in fact repeat, that is, the same error
made to different children?

17 A. Well, I suppose if you define
18 the type of error. I could think of a situation where
19 an error would be repeated, yes.

20 Q. Well, obviously what I am
21 interested in is whether or not the children could
22 have received digoxin in error in this particular
23 Hospital during this particular period of time.

24 A. As a frequent repeated event?
25



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Q. As an infrequent but repeated event?

4

5

A. I suppose that is a possibility.

6

7

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9

Q. Were you aware that there was in January of 1982 on a different ward in this Hospital, that is, on 7F, and this is reported in the Dubin Commission, five instances where epinephrine was given for Vitamin E in error?

10

11

A. Yes, I was aware of that, I recall reading that.

12

13

14

Q. And those would then be entirely separate babies, so, presumably in theory separate events?

15

16

A. As I recall, I don't remember the details, but as I recall they were individual infants on that particular ward.

17

18

19

Q. And in a fairly short period of time, that is, I believe in about a week's time the error occurred five times.

20

21

22

A. I will have to take your word for that; I don't remember the time course of it because I just don't recall but I will take your word for it.

23

24

25

Q. Well, this is in Chapter 13



1
2 of the Dubin Report. But would you agree that that
3 kind of error is unlikely, that is, five babies
4 being given epinephrine instead of Vitamin E in the
5 same week?

6 A. Yes, I think it is an unlikely
7 event.

8 Q. But nevertheless it occurred.

9 A. It did occur in that instance.

10 Q. Would you agree with me,
11 Dr. Kauffman, that the possibility of medication
12 error increases if there is confusion or stress on
the people who are part of the system?

13 A. I suppose the probability
14 for an error occurs during periods of stress.

15 Q. Would you agree with me the
16 possibility for error increases when there are
17 multiple administrations of different medications,
18 say, in a short period of time?
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A. I don't really know, but I expect that it is reasonable, that the probability would increase with multiple administrations over a short period of time.

Q. And will you agree that the possibility for error may increase if medications are borrowed from another floor?

A. I think that is a bad practice that would lend itself to the potential for medication error, yes.

Q. Would you agree that medication error - the possibility of medication error could increase if there were predrawing of medications?

A. Well, I don't know that that is the case. I don't know that that in itself increases the risk of medication error. Because predrawing - labelling of drugs for administration is a part of a unit dose intravenous-mixture program, where the medication is drawn into the syringe and delivered to the floor for administration to the patients. I don't know that that in itself increases the risk.

Q. Would you agree with me that if the people deviated from the accepted, or the normal system in that hospital, that that can cause error?

A. I think any deviation from the



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standard of practice will increase the probability
of error.

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Q. So if there is not a unit dose
system there and they deviate from that that would
possibly increase the chance of error?

5

6

7

A. Deviate from the unit dose
system?

8

9

10

11

12

Q. If there is not a unit dose
system there, and that is the normal practice, is
the drawing up of medications at the time of
administration, if that is the normal practice you
would agree with me that deviation from that could
cause error?

13

14

A. It could if they don't label
the containers into which they pour it.

15

16

17

18

Q. And when you were doing your
report I gather you were aware that The Hospital
for Sick Children on these wards used the medication
ticket system as opposed to the unit dose system?

19

20

21

A. I was aware that they did not
have a unit dose system. I did not know the details
of the system that was in place. I was aware that
they did not have a unit dose system.

22

23

24

25

Q. And were you aware that the
unit dose system was instituted some considerable



B.3

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time after the epidemic period?

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A. Yes.

4

MS. SYMES: Those are my questions, sir.

5

THE COMMISSIONER: Thank you. I don't
see Mr. Olah or Miss Jackman. Mr. Labow?

6

CROSS-EXAMINATION BY MR. LABOW:

7

Q. Good morning, Doctor.

8

A. Good morning.

9

Q. My name is Stephen Labow and I
represent a number of parents in this matter.

11

Now, you have told us that you devised
the criteria of your rating system yourself?

12

A. For the Centers for Disease
Control.

14

Q. For the Centers for Disease
Control.

16

A. I devised the criteria, yes.

17

Q. Now, did you devise that
criteria before you reviewed the charts?

18

A. Yes.

19

Q. But after you had seen
Dr. Hastreiter's summaries?

21

A. Yes.

22

Q. So you had some idea of the
children and the charts that you would be dealing with?

23

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B.4

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A. Yes, I did, I knew the nature of the cases.

Q. Now, Mr. Commissioner, this is Exhibit 272, Tab 1, the criteria are on page 3 of the December 14 letter.

THE COMMISSIONER: Exhibit 272, what is 272? Oh, yes, that's right.

MR. LABOW: Q. Now, am I correct, Doctor, in saying that a patient or a child could not fall into Rating No. 5 without some kind of post mortem digoxin data, be it tissue or serum?

A. I think that that is correct looking at the criteria here, they would either have to have 4 of the 5 criteria present, they will either have to have one or both post mortem - well, I am sorry, I am looking at Criterion 3. The only criterion that calls for post mortem autopsy, for post mortem tissue data, is Criteria No. 4, and I suppose that it would be practically impossible for a patient to fill all the other criteria and not fulfill that one.

Q. On Rating No. 5, No. 3 says that post mortem serum is well above the therapeutic range. No. 4 says digoxin concentration in fresh autopsy tissue is in excess of those reported of



B.5

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patients receiving therapeutic doses?

3

A. Right.

4

Q. So you would have to have some
kind of post mortem digoxin level?

5

6

A. Oh, I thought you were
specifying tissue?

7

Q. No.

8

9
10

A. Yes, you would have to have
some kind of post mortem digoxin data to fulfill
that.

11

12

Q. So, without that data a child
could not fall into that category under any circum-
stances?

13

14

A. I think that is correct.

15

16

17

Q. Can you point out to me what
kind of clinical course, in general terms, is highly
suggestive of digoxin toxicity; what would you be
looking for?

18

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A. I was looking for evidence of
a rather sudden change in their clinical status
which might involve change in heart rate, or heart
rhythm, central nervous system status, feeding status,
vomiting, I think those are in general the criteria.
I was also looking at any evidence in their clinical
laboratory, clinical chemistry reports of anything



B.6

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that might be consistent with digoxin intoxication,
or evidence that would be against that.

4

Q. Now, with regard to Rating No. 3,
it is only possible for a child to fall into that
rating if they were not prescribed digoxin?

6

A. I think that is correct.

7

8

Q. Now, Doctor, you did your
original chart review or your ratings, rather, on
the 19th of November, is that correct?

9

10

A. I don't remember specifically
but that sounds approximately correct.

11

12

Q. Some time though in November?

13

A. I believe so.

14

Q. And your report to the Police
in December, and then your revision in January, is
that correct?

15

16

A. That is correct.

17

Q. Now, Doctor, you said there

18

was very little difference between Ratings No. 1 and 2?

19

A. That is correct.

20

Q. And both of those are relatively
low suspicion?

21

A. That is correct.

22

Q. Now, if I put to you certain

23

symptoms and the clinical course of certain children

24

25



B.7

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who you rated in Rating No. 1, and they had digoxin ratings that were consistent with therapeutic digoxin doses, they could just as easily I assume fall into Rating No. 2?

5

A. They --

6

Q. I am sorry.

7

A. Go ahead.

8

Q. Because Rating No. 2, Rating No. 1

9

and No. 2 says a clinical condition and course not inconsistent with digoxin toxicity.

10

11

A. That is correct.

12

Q. And my understanding is the

13

symptoms are so non-specific that in most of the

14

cases we have dealt with the clinical course is not inconsistent with digoxin toxicity?

15

A. In the majority of them, some

16

of them have more suggestion of toxic symptoms than

17

other do, but I think in general your statement is

18

correct.

19

Q. Now, Doctor, regarding Real

20

Gosselin, you put Real Gosselin into Rating No. 1

21

based upon the second criterion there, that he was

22

receiving appropriate digoxin dose and that serum

23

and/or tissue concentrations were not inconsistent

24

with the dose.

25



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Kauffman,
cr.ex. (Labow)

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Now, Doctor, this child when he was
admitted to the Hospital from Winnipeg had a digoxin
level of 3.9 or 3.7, we are not quite sure, is that
a concentration not inconsistent with the dose?



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A. I thought it was consistent with the dose that I calculated he had been given before he was transferred.

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Q. But Doctor, in this case, Real Gosselin's terminal events were an episode of bradycardia that resolved spontaneously, another episode of bradycardia and then arrest, and he could not be resuscitated. In addition, some of the symptoms that he exhibited, and he was only in the Hospital for a few days, were vomiting, increased lethargy and arrhythmias.

12

13

Are those symptoms not inconsistent with digoxin toxicity?

14

15

16

A. Those in and of themselves are not inconsistent with digoxin intoxication or a number of other things in a child with his problems.

17

18

19

Q. Well, was there anything that made you feel that since he seemed to satisfy two of the three criterion for rating No. 2, he should not be in Rating No. 2?

20

21

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23

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A. As I said earlier, at the time that I was doing the ratings, I made a judgment at that point in terms if I had no solid digoxin data to point toward intoxication, I tried to make some judgment as to how strongly I felt at the time that



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their clinical course tipped them into one group or the other. I have not looked at the details of this child's chart for a long time, so I do not remember the details, but I suspect that there was something about this child's course that I thought was more consistent with -- that the symptoms were more consistent with what had been going on with the baby rather than digoxin intoxication in light of the doses that he had received and the concentrations that were measured.

I think even more importantly, as I pointed out earlier, I really think that there is no real difference between the babies that ended up in Rating 2 and Rating 1, and in fact, I found out later that the CDC essentially lumped them together.

Q Now, this child did not have any toxicology, any post mortem digoxin levels of any kind done, and I put to you that because of that you could not put him above Rating No. 2?

A No, I had no basis to put him above Rating No. 2.

Q Now, Doctor, could you look at Barbara Gionas. Doctor, you did rate this child in Rating No. 2.

A Let me see if I can -- I think



C.3

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I rated that baby as a No. 2, did I not?

Q. Yes.

A. Yes.

Q. But you have told us at page 5908 of your evidence in Volume 72 that her course was not typical of digoxin intoxication?

A. Pardon me, I am trying to find my summary of her course so I can refresh my memory.

I apologize because I have not had time to think about these for the recent weeks, and so I do not remember the details off the top of my head.

Q. Well, Doctor, this child went through a long stay in the Hospital, had two operations.

MR. YOUNG: Excuse me, Mr. Labow. Mr. Commissioner, I wonder if it might assist the doctor if he had a copy of his evidence? Doctor, do you have the transcript?

THE COMMISSIONER: I think he has that.

THE WITNESS: I have them.

THE COMMISSIONER: Which volume is it?

MR. YOUNG: It is Volume 72, page 5908.

THE WITNESS: 79?

MR. YOUNG: 72.

THE COMMISSIONER: What page?



C.4

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MR. YOUNG: Page 5908.

MR. LABOW: Q Starts at page 5907.

A. Okay.

Q Now, this child, on the 26th of February, was transferred from the Intensive Care Unit back to the ward after her second operation.

A. All right.

Q And she continued to go somewhat downhill, was vomiting persistently. There are notes at the back of the record that seem to indicate that there was a question -- they were questioning the digoxin therapy and they took repeated levels. For example, the level on March the 2nd was 1.9, but on March the 3rd the digoxin dosage was lessened, in any case, notwithstanding a level of 1.9. She continued on digoxin until the 7th of March, and on the 7th of March the plan was to hold the digoxin, and one of the doctors noted, one of the residents, Dr. Kobayashi, noted in the Hospital record that his impression was it was either digoxin toxicity, congestive heart failure or hyponatremia, and digoxin was held.

Now, on the 7th of March the child seemed to improve, was not vomiting any more, was comfortable, but then later on the 8th of March she



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became very bradycardic and died early on the morning of the 9th. Now, is there anything that you recall that makes her course atypical of digoxin toxicity?

A. Well, again, she is a baby whose symptoms could have been but may have been due to her severe congestive heart failure. It is difficult to say just based solely on her symptomatology; it is, I think, impossible to say which it may have been with any certainty.

I suspect that the fact that she had serum concentrations pre mortem that seemed to be consistent with the dose she was receiving but had some post mortem levels that were difficult to interpret led me to put her in the Category 2 group.

Q. Now, you have told us that her post mortem concentrations, and these were exhumed embalmed tissue concentrations, were ambiguous. Were they as consistent with digoxin toxicity as not?

A. They could be consistent either with toxicity or non-toxicity, depending on what other data you might have.

Q. Now, the doctors seemed to be somewhat concerned, one of the doctors, in any case. Did her disease, in any way, predispose her to digoxin toxicity?



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A. She was a baby with severe high output failure. She was not cyanotic, as I recall. She had severe high output congestive failure that really was not amenable to medical therapy or her surgical intervention. To the extent that her heart was dilated and in a sense overworked, I suppose it is conceivable. I do not think that she had any inherent dysrhythmias or any hypoxia to predispose her to digoxin toxicity.



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I wouldn't have expected her to be any more sensitive to digoxin intoxication than any other baby with high output congestive failure.

Q. Now, Doctor, without fixed tissue or post mortem serum I take it you really couldn't place her any higher than Rating No. 2?

A. I think that is correct. I think she had fixed - not fixed tissue, she had exhumed tissue concentrations, yes.

Q. That's right, she had exhumed tissue?

A. Yes.

Q. Now, Doctor, I would like to deal with Kristin Inwood.

Doctor, in your first report on page 11, and this was your December 16th letter, you comment that in this case the fixed tissue was somewhat high but inconclusive and there was hyperkalemia, which was consistent with digoxin intoxication. In fact, could I take it from your evidence that you were still not very sure though where to place this case?

A. Well, I think that at that time - are you talking about the CDC?

Q. Yes.

A. You are talking about the Police Report now.



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Q. Yes.

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A. Well, I think I indicated in my report that I thought that this case was suspicious, that there were several things that were consistent with digoxin intoxication but that because the uncertainties of the tissue concentrations in the fixed tissues I had to be careful in terms of the certainty that I expressed this.

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Q. Now, Doctor, you later received the sample of 491 nanograms in serum that we have had a lot of discussion about and that seems to you to be very supportive and you changed your view somewhat in your January 17th letter to Mr. Wiley, and that was the note, and I think it is page 3, where you comment that even if you assumed that the actual concentration at the time of death was one-tenth the measured concentration, that would still be consistent with a lethal dose?

18

A. Yes.

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21

Q. Now, Doctor, you comment at the end of your note that you had some concern about the high concentrations in fixed tissues?

22

A. Right.

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Q. Now, this child had been receiving digoxin at the hospital she was at previously



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and it was held at The Hospital for Sick Children, although, she did receive what we have heard to be an excessively large dose by mistake. Could her prior digoxin therapy account for most of her tissue levels?

A. Well, it is difficult to answer that because of the difficulty in interpreting these kinds of samples, the concentrations in the fixed tissue, I think it was fixed tissue I believe.

Q. It was fixed tissue.

A. Yes, were higher than what were recorded in other cases in which fixed tissue was assayed, it was quite a bit higher. So, that concerned me. It is possible that chronic previous digoxin administration could produce tissue concentrations in such a range but it concerned me that in the several tissues that were assayed that they were all consistently, the digoxin concentration was consistently higher in all these tissues as I recall than in any of the other cases in which fixed tissue concentrations were determined and that was probably a major factor in leading me to be suspicious in this case.

The plasma sample then that I became aware of later simply reinforced that impression.



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Q. Now, you told Ms. Symes that even if that sample had been left in a refrigerator uncapped that you felt it would be unlikely that would reduce the digoxin level tenfold?

A. I thought that was an extreme reduction factor.

Q. So, you would consider that at the very least the serum level of this child was around 50?

A. I think at the very least, I think it is unlikely it was even that low but for the benefit of the doubt I reduced it to 1/10th and that comes out to be around 50.

Q. Now, if this child's serum level was 50, taking the very minimal, would that still be consistent with a lethal administration within about an hour?

A. It could be, depending on what other variables you want to throw into this speculation.

Q. Now, Doctor, you seem from what we were just discussing regarding the tissue levels, do you have any answer now for a very high serum level and high fixed tissue levels, a serum level of this magnitude?



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A. Of 491?

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Q. Yes.

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A. Well, it is hard to accept that,

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to explain that number at face value, it really is

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difficult. I think that probably the real post

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mortem level was somewhat less than that but I don't

8

know how much less. I think it is highly unlikely

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that it was a tenth of that, although, that is a
number I used to provide an extreme minimal calculation.

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The tissue concentrations in a child who has been on

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chronic digoxin therapy, as I said, could be

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consistent with that but are not inconsistent with a

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child receiving a large bolus of digoxin within an

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hour or two prior to her demise. The tissue levels

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are significant in that they are higher than any

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other fixed tissues in any other cases but you still

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have to be very careful about quantitative inter-
pretation.

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MR. LABOW: Thank you, Doctor. I

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have no further questions.

20

THE COMMISSIONER: Yes, all right,

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thank you.

22

Well now, Miss Jackman didn't turn up,

23

Mr. Olah, so, we passed over her and over you but I'm

24

going to come back to you unless Mr. Tobias wants to
stand down.

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MR. TOBIAS: I will require a few
more moments to gather my thoughts, Mr. Commissioner.

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THE COMMISSIONER: Yes, all right.

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Then, Mr. Olah?

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MR. OLAH: Thank you, sir.

CROSS-EXAMINATION BY MR. OLAH:

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THE COMMISSIONER: If you're asking
Mr. Olah how long he will be, I can tell you that.

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MR. OLAH: A half an hour, sir, and
then the blade comes down.

11

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THE COMMISSIONER: He is going to be
a half an hour, yes.

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MR. OLAH: It is a self-destruct
situation, I think.

15

Q. Doctor, good morning.

16

A. Good morning.

17

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Q. As I probably earlier
mentioned to you I act for a Registered Nursing
Assistant by the name of Janet Brownless.

19

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21

I would like to turn you, sir, first
to the case of Kevin Pacsai. Have you had a chance
to review the notes you made for the Atlanta study
with respect to Kevin Pacsai?

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A. Not recently but I can pull them
out.

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D.7

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Q. Perhaps we could look at
Exhibit 273. I believe it can be found at Tab 34.

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A. I'm sorry, what exhibit number?

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Q. The exhibit number is 273. Have
we got 273, Mr. Elliot?

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THE COMMISSIONER: Is it Exhibit 272?

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MR. OLAH: I apologize, 272. It is
your summaries for the Atlanta study.

8

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THE WITNESS: Okay, I have it.

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MR. OLAH: Q. If you would be good
enough to turn to the case of Kevin Pacsai, Doctor.
In particular, I would like you to turn to the comment
section on likely route, dose, time of administration.

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A. I have a copy here.

14

Q. Thank you.

15

A. Thank you.

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Q. Doctor, do you still take the
position that is outlined in that paragraph?

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A. It had to be administered during
the 21 hours after admission. Is that the paragraph
you are referring to?

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Q. Yes, that's the paragraph.

22

A. I don't think of any specific
reason to deviate from that at the moment.

23

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Q. From the fact that you are

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unable to speculate as to route except most likely
would be parenteral?

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A. Parenteral.

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Q. Parenteral.

6

A. Although, a large oral dose
hours earlier could be consistent with the findings.

7

8

Q. All right. In other words, you
are still of the view that the more probable mode of
administration would have been parenteral. By that
I take it intravenous?

10

11

A. Yes. Parenteral is a general
term for injection or anything other than oral but
the most, I think the most likely, if it was given
parenteral that it was probably given intravenously;
intramuscularly would not have been very practical.

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Q. Well, no, what I'm trying to
ascertain from this paragraph - in this paragraph you
indicated that in your view it was more probable
that an I.V. administration was the mode of admini-
stration than oral, am I correct?

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A. That is correct. I thought both
were possible but if I had to pick one over the other
one I thought that parenteral was more probable.

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Q. In fact, quite a bit more
probable because you said most likely parenteral was

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the mode of administration. Am I correct in that?

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A. Right.

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Q. All right. Do I take it that your present position today in fact is in the manner you outlined in this exhibit that the most likely route was parenteral?

6

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A. I think I would still agree with that.

9

Q. Okay.

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A. Given the uncertainties of it and my qualifying statements, I think that and my qualifying statements have to be taken together in context.

13

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Q. I understand that. You can't exclude the possibility of oral administration but the most probable scenario that you posit today is that in the case of Kevin Pacsai it was intravenous administration?

18

A. If indeed it was given.

19

Q. Yes.

20

A. I think I would agree with that.

21

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Q. All right. Because when you were examined by Mr. Lamek I believe the tenor of your evidence was that it was equally possible that it was oral or intravenous but your better view I take it is



D.10

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that it was most probably intravenous?

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A. I don't think I was examined

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by Mr. Lamek, it must have been Miss Cronk.

5

Q. Or Miss Cronk.

6

A. I would have to look in my

evidence to answer that.

7

Q. All right.

8

A. I don't remember what I said.

9

Q. All right. But I just want your

10

best evidence today on the case of Kevin Pacsai and

11

it is as we have already discussed?

12

MS. CECCHETTO: Perhaps my friend

13

could refer the doctor to his prior testimony in light

14

of the fact he has pointed out the inconsistency in

his evidence.

15

MR. OLAH: Well, I am not pointing out

16

a previous inconsistency, I want the doctor's best

17

evidence. If my friend wishes to re-examine the

18

doctor in that area she is most capable of so doing,

19

Mr. Commissioner.

20

THE COMMISSIONER: Yes.

21

THE WITNESS: And I think my opinion is

22

that it could have been either, that if I was to choose -

23

if I was to speculate, to pick one route over the

24

other one I would pick parenteral over oral but I

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think the two are possible.

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Q I understand that, thank you.

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Now, assuming mode of administration being by way of I.V., I take it that the - what is the point that you take it back from, Doctor, is it the first symptom or is it the arrest that you calculate back from for your time of administration?

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A. On Pacsai?

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Q. On Pacsai.

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Q. What I would like to discuss with you, Doctor, is what is the maximum window, or the time, taking it back the furthest, at which an administration of intravenous-oral, or intravenous digoxin could have been administered to this child in a lethal dose.

I would like to know, first of all, what point do we take from which we calculate back?

A. Well, this has the same problems and vagaries as all the other patients we tried to deal with this question; that is whether you define death at the point that the arrest occurs; or at the point life threatening dysrhythmia occurs; or at the point in time when the resuscitation team decides they can't do any more for this patient and decide to pronounce him dead.

As I think I have stated previously, death is probably occurring in and continuing during that period of time, so it is hard to define the actual time of death. I don't remember offhand the specific time frame of events here.

Q. Let me help you, Doctor.

The arrest occurred at 8:45 a.m. and the child was pronounced dead at 10:10 a.m. You will recall that this child was transferred from the ward to ICU at



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6 o'clock in the morning.

3

A. Okay.

4

Q. And shortly thereafter the

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ante mortem sample was taken.

6

A. Right. Okay. Well, again I

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don't think, I don't think I tried to pin down a

8

window based on a definition of the time he died,

9

because I thought that there just was not enough

10

data to pin down a narrow window in this child.

11

I suppose if I had to I would say

12

that his critical event was at the time that he

developed his arrest at 6:30, or whenever.

13

Q. He arrested at 8:45 a.m.

14

A. He was having problems long

before that.

15

Q. No question about that.

16

A. That is why it is a problem

17

for me, because he was having problems with

18

dysrhythmias for several hours prior to that, and

19

then finally had a full cardiac arrest at 8:45. I

20

don't remember exactly how long the resuscitation

21

effort resumed, it was a little over an hour I think.

22

Q. It was from 8:45 to 10:10.

23

A. So it was an hour and a half

approximately. So death, you know, could have

24

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E3 1
2 assumed any time in there, but he was having symptoms
3 several hours before that arrest with hyperkalemia
4 associated with it, which to me is evidence consistent
5 with digoxin intoxication being present several hours
6 prior to the actual arrest. I don't know if this is
7 responsive to the question you are asking, or not.

8 Q. Just so I can tell you,
9 Doctor, what I am trying to achieve. I would like -
10 my client went off duty the evening prior at about
11 7:30 in the evening, all right. What I'm trying to
12 ascertain at this stage is the maximum window, the
13 maximum time back at which an IV dose, lethal dose
14 of digoxin could have been administered. Now, in
15 order to get at that time, the maximum time back,
16 you and I have to have a point of departure. What
17 I am trying to ascertain is do we calculate back
18 from the time of death, time of arrest, or from the
19 time that first symptoms of digoxin toxicity appear?

20 A. Well, I didn't look at this
21 case that way. I looked at the time that he was
22 admitted to the Hospital, and I said, you know,
23 looking at how things progressed it could have
24 happened any time after 8:00 p.m., now ---

25 Q. I understand how you looked
at it for that report.



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A. If I had to pick a time that he may have been exhibiting signs of digoxin intoxication it may have been as early - he may have started exhibiting signs of digoxin intoxication as early as 3:45 a.m. when his condition suddenly changed.

Q. Well to be fair, Mr. Commissioner, and I have pointed this out, that is actually 4 o'clock, the notations are from 3:45 on.

A. Okay.

Q. But the actual notation with respect to symptoms is 4 o'clock.

A. Okay, I will accept that. You know, the earliest that he might have been exhibiting signs according to the description and the chart was around 4 o'clock in the morning.

Q. Would you agree with evidence we have heard earlier, that with respect to intravenous administration, that one would expect to see signs of digoxin toxicity anywhere from half an hour to five minutes before the symptoms occur, does that range seem acceptable to you?

THE COMMISSIONER: I'm sorry, what was the question?

MR. OLAH: I am sorry, anywhere



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THE COMMISSIONER: What do you expect him to - are you talking about the dosage or talking about the time of administration?

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MR. OLAH: I am talking the time of administration, yes.

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THE COMMISSIONER: The time of administration, yes.

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MR. OLAH: Q. We have heard evidence, Doctor, that symptoms are - generally appear, symptoms of digoxin toxicity anywhere from 5 to 30 minutes after the administration of a lethal dose of digoxin; do you accept that time frame?

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A. I think they can appear during that time. It depends a great deal on the dose, the dose, the rate at which it is infused and a number of other variables that one has to define. In fact, if I remember right there are a couple of case reports I have read where it was longer than that that there was a documented overdose. So I suppose those could be the range of the closest time that you might expect some symptoms, I think it could be longer than that possibly too.

Q. What is the longest period that you would take it back, Doctor, bearing in



1
2 mind we are talking about a lethal dose of
3 digoxin?

4 A. Well, a lethal dose is not
5 a very tight definition. It could be a tenfold - a
6 lethal dose in one patient is not a lethal dose in
7 another patient, and that really doesn't define it
8 for me.

9 Q. I'm afraid we can't be more
10 specific; but also bearing in mind that this child
11 was honourable given the previous problems it had.

12 A. That is right. He was
13 probably more susceptible than most others - than
14 a lot of other babies at least because of his
15 inherent arrhythmias.

16 Q. Bearing in mind those two
17 factors, that we have got a lethal dose and we have
18 a susceptible child, I can't assist you any further
19 than that in terms of dosage. What is the maximum
20 time that you would take it back in terms of intra-
21 venous administration?

22 THE COMMISSIONER: Let me get some
23 help from him. We are dealing with Kevin Pacsai,
24 insofar as you can - are we not?

25 MR. OLAH: Oh, yes, absolutely.

THE COMMISSIONER: As far as you



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3 can use the facts of this child, if you can help us
4 as to when the earliest time of the administration
5 of a dose was. We are not dealing with a reading
6 of 491, we are dealing with a reading in the 20's.

MR. OLAH: Absolutely.

7 THE COMMISSIONER: And we are dealing
8 with the start of symptoms at 4 o'clock, assuming
9 that. You can assume anything else you like, if
10 you can reach a time, the earliest time at which
11 a dose could have been administered.

12 THE WITNESS: If it was given, if
13 we accept that 4 o'clock is the earliest onset of
14 symptoms and those symptoms were due to the digoxin,
15 I think that the dose, if it were given intravenously
16 could have been given anywhere within - oh, an
17 outside number is very difficult to come up with
18 and defend, but I suppose 1 to 2 hours at the longest
19 for - in this patient, if he got a single bolus
20 of digoxin big enough to cause the symptoms that
21 were observed and the concentrations that were
22 observed post mortem. We do know that there was
23 some fair amount of digoxin in his lungs, a relatively
24 high concentration, so some distribution had to take
25 place at least in the lungs. So that there had to
be some type of distribution, so that takes us



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2 longer than 5 minutes in my opinion and probably
3 somewhere out to at least an hour, if not a little
4 longer, but this is very speculative.

5 MR. OLAH: Q. I understand that,
6 and if we are taking the time at which the first symptoms
7 are exhibited as the time for calculating back.

8 A. When I did this exercise
9 just now?

10 Q. Yes.

11 A. Yes.

12 Q. All right. Now, I would like
13 to then turn to possible oral administration,
14 Doctor; and we have had evidence from Dr. MacLeod
15 that with respect to oral administration he would
16 anticipate seeing symptoms anywhere from 1½ to 2
17 hours after the administration of an oral large dose
18 of digoxin; and for my friends it is at Volume 63,
19 page 4141.

20 Dr. Spielberg on the other hand
21 testified that the range in his opinion with respect
22 to oral administration would be 1 to 3 hours.
23 Dr. Hastreiter testified --

24 THE COMMISSIONER: Before you go
25 on, Mr. Olah, I have expressed my views on this
kind of cross-examination before. I would much



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3 prefer to have Dr. Kauffman, he knows it, I would
4 much rather have your views on the matter rather
5 than your confirmation of other doctors. I have no
6 objection, this may well be fair in the sense that
7 he won't be disturbed by it, but it helps me more
8 if I get his view than if I get his confirming of
other views.

9 MR. OLAH: I understand,
10 Mr. Commissioner, and I am simply putting these
11 pieces of evidence to him so he has all the
12 evidence and then I am going to ask for his
independent opinion.

13 MR. SCOTT: You should have given
14 Mr. Olah formal notice you see.

15 THE COMMISSIONER: Yes, that is
16 right.

17 MR. OLAH: Formal notice that I
18 should ---

19 THE COMMISSIONER: Yes. Well, at
20 any rate I managed to get my views through to you
21 if you want to hear what Dr. Hastreiter said too
22 before you venture an opinion that is fine by me,
but I really want your own, not his.

23 THE WITNESS: Well, my curiosity
24 is piqued now, but I will try to give you my own
25



1
2 independent views.

3 THE COMMISSIONER: All right.

4 MR. OLAH: Q. Dr. Hastreiter on the
5 other hand was of the view --

6 THE COMMISSIONER: You are not
7 going to get a chance.

8 MR. OLAH: Q. Well he said his
9 appetite was whetted, so I am salivating it there.
10 Dr. Hastreiter was of the view that it would be
anywhere from 30 minutes to 2 hours.

11 Doctor, what is your best opinion
12 as to the maximum window with respect to the earliest
13 time for oral administration?

14 A. The earliest time? Well, I
15 think all the ranges that you have just quoted me
16 make the point that it is very difficult to do this
17 because there are a lot of vagaries and variabilities
18 involved in oral administration and absorption. In
19 a given child with no data you can just almost
speculate anything based on what has been reported.

20 Q. Right. Let me just posit
21 one more thing.

22 MR. YOUNG: If he could just finish
23 his answer.

24 MR. OLAH: Q. May I make just one
25



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2 more point, we are talking about the Pacsai child
3 now, Doctor, all right?

4 A. That is right, but we don't
5 have any data on this child so the best we have to
6 do is say, what is the wide range that has been
7 reported with oral intoxications in the literature.

8 There have been a few children reported
9 to my recollection who have taken oral digoxin in
10 overdose who have not shown any symptoms for 5, 6,
11 7 hours. There is one little boy I recall reported
12 in the literature that came in two days after he had
13 taken digoxin overdose, with symptoms, that is an
extreme.

14 If the digoxin was given to this
15 baby as a liquid form, as the elixir, or as the
16 liquid IV preparation but given orally, I would
17 expect the symptoms to occur earlier than 6 or 8
18 hours because the absorption from a liquid prepara-
tion is generally faster than it is from tablets.

19 So I have to accept that it is
20 possible that symptoms could occur within a couple
21 of hours after, probably, if you want me to give you
22 another I will say two hours, and it could have been
23 as long as 4 to 5 hours I think, orally. Or, if it
24 was given in several oral doses over a period of
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time it could have been even longer than that.

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Q. Given all of the facts that

we are aware of with respect to the Pacsai child;

namely the distribution in the tissues; the lengthy

time between the first symptoms and the arrest and

death; or do you see that last scenario, that

multiple oral dose as being likely?

A. Being likely?

Q. As being likely?

A. I suppose I see it as being

as likely as a single oral dose except it would

take more of an effort on somebody's part to do it,

or more errors involved, which makes it somewhat

unlikely. It would make it a little easier because

you wouldn't have to give such a large volume each

time. So there are probabilities that weigh against

each other in trying to say which is more likely,

a single oral dose or several individual doses given

a few hours apart.

Q. Going back to the ultimate

question, what do you perceive to be the earliest

time for administration under these two modes,

did I understand you to say somewhere in the range

of 4 to 5 hours?



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A. I think an outside number could be that long, if it was given as a single oral dose of a liquid preparation.

Q. Doctor, I think you have already said, turning to the Inwood child, that oral administration with respect to that child was unlikely and that consequently you see, I take it, I.V. administration as being the most likely route or mode of administration with respect to that child?

A. I think I said if I had to choose between the two I would say that was a little more likely, yes, or somewhat more likely.

Q. Now, in the Inwood case arrest occurred at 2:30 in the morning and death at 3 o'clock in the morning. I take it that going through the same exercise we just completed with respect to the Pacsai child but applying it to the Inwood child, what is the maximum time or the earliest time at which a lethal dose of the kind we have talked about would have occurred with respect to this child?

A. The longest time before the onset of the arrest?

Q. Yes.

A. Well, under that scenario we have to allow for some significant amount of tissue



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distribution. We also have the problem of a very
high serum concentration which may or may not be
correct.

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I think allowing for the tissue
concentrations that were observed, albeit they were
difficult to interpret because they were fixed, but
we have to assume some distribution, I would have to
make it longer than an hour, and again, this depends
on the size of the dose given. If it was given as
a single intravenous dose, I think it is unlikely
that it was given longer than three or four hours
prior to the onset of the symptoms.

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Q So that if my client were off
the evening previously at 7:30 in the evening, I take
it, Doctor, she could have had no direct involvement
with respect to the death of this child?

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A Well, I suppose I could answer
that to the extent I think it is somewhat unlikely.

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Q Highly unlikely, Doctor?

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A I will agree with you.

Q Doctor, I would like to go back
to your Atlanta notes, summaries, and I would like
to just deal for a moment, if I may, with respect
to the Lombardo child. Again, I would like to turn
you to your comments on likely route, dose, timing
of administration.



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A. I have that sheet in front of me.

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Q. There you indicated that in your

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opinion I.V. bolus or rapid infusion shortly before

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death, 30 to 60 minutes. Doctor, I was just curious,

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how could you arrive at or how, in fact, did you

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arrive at that opinion?

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A. I think it was based to a large

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degree on the description in the chart of her having

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been apparently fairly stable and suddenly having a

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change in her clinical condition, which were symptoms

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which were suggestive of digoxin intoxication.

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According to my notes I have here, over a short

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period of time she developed an irregular heart rate,

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bradycardia, weak pulses, she vomited, developed

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ventricular fibrillation, did not respond to

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resuscitation efforts, and I think in a baby who

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appeared -- she was not well but she appeared to be

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relatively stable, suddenly had these kinds of

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symptoms develop, and I thought that the most likely

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scenario was that if digoxin was given in an overdose

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it was probably given within an hour prior to the

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development of sudden onset of these symptoms.

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Q. And I take it that is still

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your opinion today?

A. I think so.



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Q. Thank you. Similarly, I would like to turn you to the Belanger child, your notes on the Belanger child, again to the comment section.

A. Okay.

Q. And there you indicate that if it was administered on 4B, it would have had to have been within five hours of death. Was that based or predicated upon the time at which the child was transferred to the floor?

A. Yes, that was simply because the child had not been on that ward prior to that.

Q. Doctor, I would like to then turn you to the Hines child, if I may.

A. To the CDC report on Hines or Hines in general?

Q. Yes, I would like to first turn to the CDC report, and there you indicated that you were unable to speculate as to the likely route, dose or timing of administration.

Doctor, given all of the information that you have assembled to date with respect to the Hines child, are you in any better position today to render an opinion as to likely route of administration than what you were when you assembled a report for the CDC?



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A. I really do not think so. We have very, very minimal laboratory information, digoxin information on this child, and if there was no digoxin present on the exhumed or the fixed tissues on this baby, I think that there is very little else that would have suggested to me that this baby suffered from digoxin overdose. The fact that it was present and he had not been prescribed digoxin I think were a significant combination of factors that led me to rate this child as a probability of 3.

Q. Doctor, the time parameters that you and I discussed relating to the Pacsai child, the windows, as I have called them, can they be applied also to the Hines child?

A. There just is not the same degree of clinical or laboratory information on this child that there is with Pacsai, and it is considerably more speculative to try to place a window on this child, and that is why I did not attempt to do it earlier.

I understand your problem but I have a problem too --

Q. I understand.

A. -- in trying to give you opinions in a vacuum.



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Q Well, Doctor, bearing in mind that the Hines child arrested at 4:10 in the morning, do you see a lethal intravenous dose being given any earlier than, say, three hours prior to the arrest; do you see it as being probable?

A I suppose if I had to answer the general question of if you give an intravenous bolus of digoxin in an overdose to an infant are you likely to see symptoms within three hours, I would say yes. Do you understand my answer?

Q I understand your answer. I am not sure that it really ---

A But we did not have enough information in this patient to really pin anything down. All we had was a baby who had a lot of other reasons to have arrhythmias; he looked septic and was very sick and in whom digoxin was found after death in tissues.

Q All right. Assuming hypothetically that in fact an I.V. mode of lethal dosage of digoxin did in fact cause the death of this child, do you see such a dose being administered any earlier than three hours back from the time of arrest, Doctor?

A I can answer to the extent I think it is unlikely.



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Q And similarly, with an oral dosage, can we go back to, I believe it was five hours you said in relation to the Pacsai child?

A It would be longer with an oral dose.

Q Can you see it as being more than five hours?

A I think it is unlikely.

Q Thank you.

THE COMMISSIONER: I think that is it, Mr.Olah. There may be some time at the end of the morning.

MR. OLAH: I have just one more question, Mr. Commissioner, but if ---

THE COMMISSIONER: No, no, if it is just one more question, that is fine, and it will have to be a long question, I guess.

MR. OLAH: Q Doctor, with respect to the Lombardo child, you will recall that in Exhibit 95C, that is the Report of the Centre of Forensic Sciences, stomach contents of 629 nanograms were found at Sample T-60, T-61 small bowel was 280 nanograms. I believe those are total values?

A I think they were total quantities found in whatever the contents were.



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Q. The simple question I had was those readings, do they assist you at all in ascertaining whether, in fact, the mode of administration, assuming lethal dose causing death, whether that mode of administration would have been oral or intravenous?

A. They really are not helpful because ---

Q. Are they neutral then?

A. I suppose they are neutral. I think I really took them into account very little, if any.

MR. OLAH: Thank you, Doctor. I am very grateful. Thank you, Mr. Commissioner.

THE COMMISSIONER: Mr. Tobias?

CROSS-EXAMINATION BY MR. TOBIAS:

Q. Yes, Doctor, my name is Warren Tobias and I act for the family of the infant Jordan Hines.

In giving evidence when you were last here, Doctor, you made several references to the Sudden Infant Death Syndrome, and I believe it is fair to say that in summary you had indicated that in your view that was a syndrome without specific pathology. I wonder if you might just elaborate for



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us on specifically what you meant by the phraseology
'a disease without specific pathology'?

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A. I think that sudden infant death
is a diagnosis of exclusion. Clinically to me
sudden infant death occurs in an infant who is
perceived to be essentially well prior to death and
is suddenly, for unexplained reasons, found dead
usually associated with sleep, usually no sign of
a struggle, and maybe a little bit of secretions or
vomitus in the mouth, but very little else.

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Pathologically there are a number of
findings that have been reported associated with
babies who have died under these conditions, and I
think those have been described previously. I think
they are all consistent with sudden infant death,
and they may at some point in time in the future turn
out to be very important in helping to positively
diagnose.

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My feeling at this point in time is
that although the pathological post mortem findings
that have been associated with babies who died
suddenly and unexpectedly are consistent with that,
they in and of themselves do not positively diagnose
sudden infant death; they may suggest it, they may
support the clinical findings, but if there are a



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number of contrary findings they do not invalidate all of the contrary findings. What I am saying is that I do not think there is any clinical or pathological finding that is a sine qua non of sudden infant death.

Q. Now, if we were to exclude in a case of suspected Sudden Infant Death Syndrome the clinical factors, in other words, if we were to give you a pathology report indicating only what the pathology findings were and if we were to blind you with respect to the clinical history of that particular patient and give you absolutely no information with respect to measuring the pathological findings against that background, in your view, would it be possible to definitively call that death Sudden Infant Death Syndrome?

A. I am not a pathologist, but I do not think I could positively and definitively say that that is sudden infant death, regardless of any other information.



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3 I think that it would be reasonable
4 under those circumstances to say this is highly
5 suggestive of sudden infant death and if the other
6 information available is consistent with sudden
7 infant death then it is.

8 Q. All right. Now, specifically
9 with respect to the Hines case, what other informa-
10 tion was there in that chart when you reviewed it
11 yourself which caused you to reject as a realistic
12 possibility the diagnosis of Sudden Infant Death
13 Syndrome?

14 A. Because this baby had been
15 sick for a little over two weeks, as I remember,
16 prior to his admission here. He had been seen on
17 I think two occasions with some bouts of apnea, he
18 was found to be bradycardic on several occasions,
19 he was listless, he had poor feeding both at home
20 and after his admission, he had an elevated tempera-
21 ture and he looked for all the world like a septic
22 baby, although, I guess his cultures were negative.

23 He had dysrhythmias occurring, he
24 had apnea occurring prior to and I think after his
25 admission but I'm not sure about the after admission,
I would have to look at his chart.

This baby had other things going on



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for several weeks prior to his admission here. A baby who looks as sick as this baby and then dies, in my judgment is not a sudden infant death, he died from some pathological condition and that is what makes me think he was not a typical SIDS.

Q. All right. Now, you used the phrase dysrhythmia and we have heard the phrase used many times in connection with this baby arrhythmia. Do I take it those are one and the same thing?

A. Well, I think our intent - it is just a semantic difference. I think our intent is the same. Arrhythmia to me means absence of rhythm, dysrhythmia means an abnormal rhythm.

Q. All right.

A. So, I think that people interchange those and use them interchangeably but I choose when there is a rhythm but an abnormal rhythm to denote it as a dysrhythmia.

Q. All right. Now, whether we call it dysrhythmia or arrhythmia is there anything specifically relating to this child's history with respect to arrhythmias that causes you any difficulty with the Sudden Infant Death Syndrome diagnosis?



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A. Well, his bradycardia, his paroxysmal atrial tachycardia with conduction block. A baby who has that kind of abnormality is at higher risk for a fatal dysrhythmia or fatal arrhythmia, if you will, and if that kind of baby dies suddenly I think it is difficult to say that that is a SIDS death because you have other pathology to explain the death.

Q. All right. Now, are you aware of the fact that with respect to infant Hines there was never an opportunity to perform a conduction study on the heart?

A. I wasn't aware that there was no opportunity to do that.

Q. In the absence of such a study can we really draw any specific conclusions as to the role that conduction problems may have played in his death?

A. Well, it is difficult to draw any definite conclusions. I think all you can say is that a baby who has a variable rhythm abnormality such as this baby had is at higher risk for sudden death.

Q. All right. Now, we have seen evidence in this baby of both bradycardia and



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tachycardia in association with and closely related to the apneic episodes. With respect to those two particular symptoms, bradycardia and tachycardia, do you find one any more or less inconsistent with a diagnosis of Sudden Infant Death Syndrome than the other?

A. Not particularly. I think that they both reflected a baby with a basic underlying rhythm and conduction abnormality.

Q. Well, let me assist you, Doctor. We have heard evidence from Dr. Becker before this Commission that bradycardia is something that can be seen with respect to a Sudden Infant Death Syndrome child but the tachycardia is less so, less commonly associated with that kind of syndrome, and that to a degree bothered Dr. Becker, and that was confirmed with Dr. Hastreiter's opinion. Do you agree with those observations?

A. Yes, in general I would agree with that. I think bradycardia, episodes of unexplained bradycardia, if the baby happens to be monitored, or more commonly seen in a baby who may be predisposed to apnea than the the paroxysmal atrial tachycardia that this baby had at some point in time.



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Q. All right. Now, specifically

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with respect to the four markers or pathological

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indicia which were found in the Hines baby, I would

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ask you to comment on extramedullary hematopoiesis.

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Is that something that you think is specific to the

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Sudden Infant Death Syndrome?

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A. I don't think it is specific

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to it, it is associated with it. Extramedullary

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hematopoiesis is a normal phenomena in the fetus and

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may carry over into very early infant life. This

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baby was a couple of weeks of age I believe.

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Q. I believe 23 days of age.

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A. Almost a month of age.

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Q. Right.

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A. So, it is conceivable that

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he might have had some extramedullary hematopoiesis

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residual from fetal life at that period in his

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life and I don't think it is specific for any

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specific disease entity including Sudden Infant

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Death Syndrome.

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Q. All right. Now, the possi-

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bility of the child showing that as a residual

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symptom, I take it the younger the child the more

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likley that is?

A. Yes, that is correct.



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Q. All right. So that in the case of Jordan Hines where we have a neonate that finding in and of itself is not a particularly surprising finding?

A. If I saw it in a six month old it would be much more important to me than seeing it in a three week old.

Q. All right. Dr. Hastreiter gave us evidence last week with respect to brain stem scarring, brain stem gliosis and he said that this is often seen in children who are hypoxemic and cyanotic. Do you agree with that observation?

THE COMMISSIONER: I don't know whether you were here when I attacked poor Mr. Olah for that kind of question.

MR. TOBIAS: Yes, I was and I heard that, Mr. Commissioner.

THE COMMISSIONER: Yes, all right.

MR. TOBIAS: Notwithstanding the fact that I totally disregarded it I did hear it and I must apologize, sir.

THE COMMISSIONER: Well, at any rate, it has been put to you.

THE WITNESS: To agree or not to agree.



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THE COMMISSIONER: To agree or not to agree and I just hope that you will pay as little attention as possible to it. I know it is very difficult when someone puts another medical opinion to you. I would like your own view if I may.

MR. TOBIAS: This is akin, Mr. Commissioner, I suppose to closing the barn door after the horse has exited but I will try and rephrase that.

Q. In your experience can we see brain stem gliosis in children other than candidates for Sudden Infant Death Syndrome?

A. I really don't know in all honestly all the causes for brain stem gliosis but it is not limited to babies with Sudden Infant Death Syndrome. There are many causes for recurrent or chronic hypoxia or intracranial bleeds in small infants and the glia cells are the cells that heal locations of injury in the brain. So, anything that causes an injury can be associated with gliosis and I don't think that gliosis is limited to one disease entity, it is a non-specific finding when injury occurs in the brain.

Q. All right, fine. Now, you also gave evidence the last time that you were here



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3 that you would not necessarily equate apnea and
4 Sudden Infant Death Syndrome. I wonder if you might
5 expand on that, why do you make that statement that
6 it is dangerous to equate the two?

7 A. Well, we see a great number
8 of apnea babies at our Hospital and obviously most
9 of those babies do not fortunately succumb to
10 sudden infant death. Apnea is a very poorly under-
11 stood phenomenon in infants at this point in time
12 and I think to some degree sudden infant death is
13 too. Apnea occurs probably for more than one reason
14 in small infants. It is not an uncommon phenomenon
15 since people have started recognizing it. It tends
16 to resolve in most babies by the time they are a
17 year of age if not before and most babies who have
18 suffered apnea and are monitored go on to enjoy
19 normal growth and development after their apneic
20 episodes subside as they mature. A few babies
21 succumb to sudden infant death and the highest
22 instance I think is during the first six months of
23 life. The sudden infant death does occur in babies
24 who have been documented to have apnea. It occurs
25 in babies who have not been documented to have apnea
simply because they have not been monitored previously.
It occurs in babies of families who have had other



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3 babies who have either died from SIDS or who may have
4 had apnea and the relationship between apnea and
5 SIDS is not well defined at all and I think it is
6 dangerous conceptually at this point in time with
7 the state of knowledge that we have to equate the
8 two, they just are not equivalent. A lot of babies
9 are seen and treated and evaluated for apnea who
10 never have SIDS, fortunately. There are babies who
11 die of apparent SIDS who have never been documented
12 to have apnea prior to their death.

11 Q. All right. Now, Doctor, with
12 respect to ---

13 THE COMMISSIONER: I wonder, are you
14 changing the subject?

15 MR. TOBIAS: No, I'm not,
16 Mr. Commissioner, I was about to say I might be able
17 to finish within the three or four minutes the
18 question of apnea and then I will be going on to
19 another subject, I think that would be a more
20 appropriate time to take a break.

20 THE COMMISSIONER: Yes, all right.

21 MR. TOBIAS: Thank you.

22 Q. I understand apnea by defini-
23 tion to be the absence of breathing?

24 A. That is correct.
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Q. Is that a fair definition?

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A. That is correct.

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Q. There are obviously different
degrees of severity to an apneic spell. Am I
correct in that observation?

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A. To the extent that the absence
of breathing can persist for varying degrees and
lengths of time.

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Q. Yes, that is precisely what
I meant, and those time intervals say something to
us about the severity of the episode, do they not?

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A. Yes.

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Q. All right, fine. Now, with
respect to infants, particularly neonates, is it
uncommon at all to see brief periods of apnea?

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A. Well, it depends on how you
define apnea. It is normal for newborns to have what
is called periodic breathing. They will breath
rapidly for a short period of time, their breathing
will slow, they may have periods in which they breathe
very shallowly or do not breathe for a period of
3, 4, 5 seconds, and then they start breathing again
and then they will breath rapidly for a short time
and then this sequence will cylce. That is called
periodic breathing, that is normal.

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3 An apneic episode which lasts more
4 than 10 seconds or so is usually considered abnormal
5 apnea.

6 Q. All right, fine. Now, is
7 there any magic to that 10 second mark, is that
8 where you would set the borderline for your defini-
9 tion?

10 A. Well, that is the magic
11 number the majority of people have selected. I
12 don't know that there is anything inherently magic
13 about it.

14 THE COMMISSIONER: You said abnormal
15 apnea and that you would call that apnea, I take it
16 if it lasts more than 10 seconds. If it is less
17 than 10 seconds you wouldn't call it apnea?

18 THE WITNESS: I wouldn't define
19 it as apnea.

20 MR. TOBIAS: All right, fine.

21 Q. Now, with respect to periods
22 of apnea greater than 10 seconds which you have just
23 indicated is less common, you would define that as
24 apnea.

25 THE COMMISSIONER: Yes, he indicates
that if it is more than 10 seconds it becomes apnea.

MR. TOBIAS: Right.



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3 THE COMMISSIONER: So, you can't have
4 periods of apnea greater than 10 seconds because
5 that's the only kind you can have?

6 MR. TOBIAS: I should have said and
7 meant to say, Mr. Commissioner, greater than 10
8 seconds not less.

9 THE COMMISSIONER: Well, yes. I'm
10 sorry, but apnea by definition, at least by
11 Dr. Kauffman's definition is greater than 10 seconds.

12 MR. TOBIAS: All right.

13 MR. SCOTT: I think now is a
14 convenient time to take a coffee break.

15 MR. TOBIAS: No, I would think in
16 about three minutes, Mr. Scott. I hate to keep you
17 from your coffee, I know that you take long break-
18 fasts and dinners and short lunches.

19 THE WITNESS: Don't hold your breath
20 because that is apnea.

21 MR. TOBIAS: Q. We must be careful
22 about that, we want to take good care of you,
23 Mr. Scott.

24 A. I think we should define
25 apnea for purposes of discussion as abnormal cessation
of breathing for longer than 10 seconds and then
we can go on and talk from there.



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Q. All right. Where we see periods of apnea, particularly in a neonate, is that necessarily suggestive to you that that child will go on to either a near missed-Sudden Infant Death Syndrome or to Sudden Infant Death Syndrome?

A. I think it increases our concern, it causes us concern that it increases the possibility of that occurring and that's why we frequently bring these babies in and monitor them and do pneumograms and work them out and evaluate them and sometimes if they have abnormal breathing patterns then we send them home on a monitor so that apneic episodes can be picked up and they can be taken care of in the home. It doesn't mean that most of those babies are going to have near missed-SIDS or SIDS.

Q. All right, fine. Now, you have said something interesting. You have said that they are put on monitors in order to pick that up and deal with the situation.

A. Some of them are.

Q. All right.

A. Depending on their findings.

Q. I take it therefore, and please correct me if I'm wrong, that the monitoring



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in and of itself is a way of dealing with this
problem?

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A. It is one way that is currently
used to deal with the problem of apnea in infants.

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Q. All right. Now, this
particular child was in the Hospital being monitored
on an apnea monitor and a cardiac monitor. Is there
anything in those facts which cause you concern
with respect to the diagnosis of Sudden Infant
Death Syndrome?

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A. You mean the fact that the baby was on a monitor?

Q. Being very closely monitored in a hospital setting?

A. I think that would be a normal procedure with a baby who came in with this kind of story.

Q. All right. Do you have any views, or any information, as to whether or not it is common or uncommon for a child in that setting in fact to succumb to Sudden Infant Death Syndrome?

A. It can occur, but our hope is that in that setting, on a monitor, that periods of apnea will trigger the alarm and they will be identified quickly and the baby will be stimulated and the apnea will be reversed. So our intent is that any apneic episode does not progress to death.

Q. You say it can occur, Doctor, does it occur very often?

A. It is pretty rare.

Q. And do the statistics not in fact show that most, the great preponderance of Sudden Infant Death Syndrome babies die at home where they are not monitored?

A. That is correct.



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Q. As well, this baby could not be resuscitated, does that cause you any concern?

A. Yes, that is unusual in an apneic baby.

Q. Fine. Then lastly, Doctor, I understand from reading the chart that this baby had severe nasal congestion and in fact had to be suctioned on two occasions. Can nasal congestion of that type in a neonate, and I understand that neonates breathe through their nose, can that help explain the appearance of apneic periods in this child?

A. Yes, it can.

MR. TOBIAS: Fine. Mr. Commissioner, can we perhaps take our break now?

THE COMMISSIONER: Yes. We will take 20 minutes and then we will take you for another 10. Yes, all right.

--- Short recess

--- Upon resuming:

THE COMMISSIONER: Yes, Mr. Tobias.

MR. TOBIAS: Thank you, Mr. Commissioner.

Q. Doctor, specifically with respect to the levels in infant Hines; what I would like to do is I would like to quote you from Mr. Cimbura's January 11th, 1982 report, which was Exhibit 95A,



H.3

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2 Mr. Commissioner, and the findings are reported as
3 part of Exhibit 95A at page 6.

4 What Mr. Cimbura did, Doctor, was he
5 had a sample of heart tissue which had been preserved
6 for three months in Klotz solution. He subjected it
7 to analysis using RIA, and then refining it with HPLC
8 and then doing RIA again. The results were as follows:

9 With respect to left ventricle there
10 was 118 nanograms of digoxin and digoxinlike substances
11 found, and then subsequently when that was refined
12 he found a pure concentration of 52 nanograms per
13 gram of digoxin. With respect to the right atrium
14 he found 45 nanograms per gram of digoxin and digoxin-
15 like substances, that particular sample was not
16 refined.

17 Then with respect to the septum his
18 reading was 147 nanograms per gram of digoxin and
19 digoxinlike substances, with a refined reading of 89
20 nanograms per gram of digoxin.

21 Mr. Cimbura has given evidence before
22 this Commission that in his opinion those findings
23 are consistent with not less than 252 nanograms per
24 gram of digoxin before fixation.

25 Now you have said in your report, and
I quote from page 10 of your original letter to



H.4

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Mr. Wiley; this is Exhibit 266, Mr. Commissioner.

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"However, it is a highly significant finding that substantial quantities of digoxin were present in the tissues of an infant for whom digoxin was never prescribed. This can be interpreted no other way than that a substantial dose of digoxin was given to the infant prior to his death."

Now, taking into account, Doctor, the levels found and your own comments regarding the amounts of digoxin which are consistent with those levels, is it likely or unlikely that those levels would reflect one accidental dosage given of a therapeutic dosage during life?

A. I think if a dosing error was made in a way that the therapeutic, a single therapeutic dose intended for another infant approximately the size of this infant and was inadvertently given to this infant, I don't see any way really that that kind of dose alone could account for these kinds of concentrations. I think we have to accept that the concentrations of HPLC determined digoxin were at least that high when they were - before the tissue was fixed and was somewhat higher than that, how much



H.5

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higher I don't know.

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Q. Does it in any way affect your answer if we assume an accidental administration of a loading dose?

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A. Well, loading doses are usually given and the divided dose is over 24 hours and the first part of the loading dose would be approximately twice a maintenance dose. I still think it would be unlikely that a single one-half of a total loading dose would produce these kinds of concentrations assuming that that dose was intended for an infant approximately the size of Jordan Hines.

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Q. Is it fair then to say from that, that if we are going to explain these levels by drug error, what we are into is a situation where there had to be multiple drug error, multiple meaning 2 or more?

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A. Well, I am not sure I understand the implication in your question. But correct me if I answer - if my answer reflects a misunderstanding of your question. If you are saying medication errors would include not only the wrong patient but the wrong size of the dose, then my answer to the question is, yes.

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Q. What I also meant by indicating



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and asking that question is this: if you find that one accidental administration of a therapeutic dose is inconsistent with those levels, I would assume we would have to have more than one accidental administration.

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THE COMMISSIONER: Not necessarily.

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MR. TOBIAS: Of a therapeutic dosage.

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THE COMMISSIONER: Yes, you would certainly have to do that. If there is an error in the dose it could be an error in the amount as well.

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THE WITNESS: Yes, that is what I was implying. Either an error in amount or you would have to give multiple doses intended for another patient.

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MR. TOBIAS: Precisely.

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Q. Now, with respect to the drugs that were being administered to this child, I understand that one of the drugs that he was to receive was a drug called ampicillin, are you familiar with that?

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A. I am familiar with the drug, yes.

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Q. Evidence has been given before this Commission that in the Hospital for Sick Children that drug was available as a powder and had to be diluted.



H.7

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A. That is the standard form in which it is supplied.

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Q. What do you think the likelihood is of confusing digoxin for ampicillin?

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A. I think it is highly unlikely, if you are talking about confusing the vials as they come.

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Q. Fine. Now, I would also like to ask you this. I would like to ask you to assume for the moment that there was an accidental administration of digoxin during resuscitation. Now, I have the chart of Jordan Hines, and Mr. Registrar, if you could give the witness Exhibit 103.

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THE COMMISSIONER: I should just say I understand there is a complaint about the heat, or the lack of heat here. We have taken issue with our landlords, with the Province of Ontario. I don't know whether you can put in a good word for us?

18

19

MS. CECCHETTO: They never pay any attention to us.

20

21

22

THE COMMISSIONER: Well, all right. Well, we are doing what we can, I like it because it certainly keeps me awake.

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MR. TOBIAS: Yes, I was going to say the cold does tend to keep all of us awake, Mr. Commissioner.



H.8

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THE COMMISSIONER: Yes, all right.

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THE WITNESS: I have the exhibit.

4

MR. TOBIAS: Q Doctor, the arrest
note with respect to Jordan Hines appears at page 69
of that record, it is a very lengthy arrest note by
Dr. Costigan. We have heard evidence prior to today
that in fact the Hines arrest was about two and a
half hours; or, I shouldn't say the arrest, the
resuscitation efforts. There are numerous references
in his notes to there being no output; variable blood
pressure; can I take it that those references would
indicate a markedly restricted circulatory system?

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A. I think they would reflect a
markedly impaired circulation during that time.

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Q Now, given that scenario, do
you have any opinion as to the likelihood that we
would see the levels that we do in this child if we
had an accidental administration of the drug digoxin
during those resuscitation efforts?

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A. I think that makes it very
difficult to explain the tissue concentrations that
were observed. One has to --

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Q Do I understand your answer to
be that the markedly impaired circulatory system
makes it difficult to explain the levels?



H.9

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2 A. Well, one has to allow for a
3 significant degree of distribution into the tissues
4 after the dose is administered to account for the
5 distribution in the tissue that is observed, not only
6 the heart, but the other tissues in which it was
7 measured. That means that there had to be reasonable
8 profusion of those tissues for some time prior to
9 actual death and cessation of circulation. So it
10 is difficult for me to accept a hypothesis of
11 medication error during resuscitation and providing
12 the volume, or the quantity of digoxin, during that
13 time which could produce this amount of digoxin
14 distributed widely throughout the tissues of the body.
15 It just is difficult for me to see how that could
16 occur.

17 Q. The last thing I would like to
18 ask you, Doctor, regarding levels is this: if we
19 assume an accidental administration of a therapeutic
20 dose of digoxin orally, as opposed to by I.V., does
21 that tell us anything about whether or not we would
22 expect to find the levels that we found in this child?

23 A. Well, again, it would have to
24 be a substantial dose; it could have been given a
25 long time before death possibly, because of the time
required for absorption. There was a high



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concentration of digoxin in the liver in this baby, I believe, in the exhumed liver, but that is difficult to quantitate because of the problems of measuring the concentrations in exhumed tissues. So it is difficult based on tissue data alone to speculate whether or not the dose may have been given orally or intravenously.

Q. All right, that is fair enough.

Now, with respect to Exhibit 272, I am showing you in particular, and I am sorry, Mr. Commissioner, I can't assist you as to what page of Exhibit 272 this appears on, but it is the digoxin sample of Jordan Hines which is identified by Case No. 02057, and it would be towards the back of the exhibit.

THE COMMISSIONER: It is Tab 31.

MR. TOBIAS: Yes.

THE COMMISSIONER: And it is the last page, is it?

MR. TOBIAS: I believe so.

Q. With respect to page 2 in particular, Mr. Commissioner, where it says:

"Did digoxin intoxication appear to be the result of ... ", and you have circled "unable to determine", but I



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am somewhat troubled with respect to the other options;
"an acute event, multiple doses, pre-existing
intoxication: due to prescribed dosages"; in each one
of those you have put down a 1, which according to
your form means "no".

Did you mean to in effect, by putting
down the "no", to rule out the possibility of an acute
event?

A. No. The intention of the coding
was to indicate on the computer which of the items
I was checking. It was just simply a digital
indicator to indicate which item I was selecting. The
fact that a 1 was in front of any of the options does
not mean that it was a negative answer to that question,
it was simply that I could not respond to that
question.

Q. Is it fair to say in summary that
it was the lack of data, of toxicological data in the
Hines case which leads you to the conclusion that you
are unable to determine what the mode of administration
was?

A. Yes, I think that is the case.

Q. Now, Doctor, you have given
evidence as to what you felt this child's condition
was upon admission to the Hospital and during his



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Hospital course. You referred to the possibility of sepsis; you indicated that you were concerned with dysrhythmias exhibited by this child. On reviewing this child's chart, and I am asking you now for your opinion as a paediatrician, the symptoms that he was exhibiting and the condition that he was in during his Hospital course, is that a condition that you personally would have expected him to die from?



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A. I would not have definitely expected him to die, but I would have considered him at high risk for dying at the time he was admitted and shortly thereafter.

Q. All right. Now, with respect to your ratings, Doctor, and I am talking now about the criteria that you used on a 1 to 5 scale, specifically referring to Exhibit, is it 273, the letter to Dr. Smith -- or no, I am sorry, that forms part of Exhibit 272, Mr. Commissioner, and I am referring now to the covering letter of December the 14th, 1982.

On page 3 of that letter, Doctor, you set out what your criteria were. Now, do you agree with me that be definition in the Hines case, because there were no ante mortem serum digoxin concentrations available and because there were no post mortem serum digoxin concentrations available, nor was there fresh autopsy tissue available, that by virtue of the very definition, Jordan Hines could not have been assigned a rating of 5?

A. That is correct.

Q. All right, and am I also correct that by virtue of the very definition of what constitutes of rating of 4, and that is, I am



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3 referring now to 2 and 3, the ante mortem serum,
4 post mortem serum and/or post mortem tissue digoxin
5 concentrations, again by definition, Jordan Hines
6 could not have been assigned a rating of 4?

7 A. I agree, that is correct.

8 Q. All right. So that in effect,
9 by virtue of your lack of data on this child, your
10 lack of information to work with, 3 was really the
11 highest rating he could have been assigned?

12 A. That is correct.

13 Q. Do you find the concentrations
14 of digoxin in the fixed tissue at the levels that
15 you did find them highly suspicious in a child to
16 whom no digoxin was supposed to have been given?

17 A. Yes, I did find them
18 suspicious.

19 Q. Now, Doctor, having reviewed
20 the chart and thought about this case a great deal,
21 I am sure, in preparing to give your evidence and
22 having been examined in chief about this child and
23 cross-examined on this child, looking on the over-
24 view of everything that you know, all of your experi-
25 ence and your knowledge and all of the information
that has been placed before you, do you today still
find the SIDS diagnosis one that is difficult to



I.3

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contemplate?

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A. I do not think SIDS explains

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this child's death.

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Q. All right, fine. Again,

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against the same background of all of your knowledge and information

7

/and experience, your review of the chart and the

8

toxicologic data and all of the information that

9

has been placed before you, do you today still feel

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or are you of the opinion that this child's death

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was related in some way to an administration of the

drug digoxin?

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A. I think considering all the

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circumstances, that there is a high probability that

14

digoxin was in some way related. It may not have

15

been the primary cause, but I think there is a high

16

probability it was in some way related to this

child's death.

17

Q. All right. My last question

18

is this: given what you saw about this child's

19

inherent dysrhythmia, would that have made him more

20

susceptible to the toxic effects of digoxin?

21

A. Yes, I think so.

22

MR. TOBIAS: Thank you, Doctor.

23

Those are all my questions. Thank you, Mr. Commissioner.

24

THE COMMISSIONER: Thank you,

25

Mr. Tobias.



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2

I.4 Now, Ms. Jackman, I understand that
3 it is no fault of yours and that writs are being
4 issued all over the place because of what happened
5 here this morning, but how long do you think you
6 will be now?

7

MS. JACKMAN: I think I may be able
8 to finish by one o'clock, Mr. Commissioner.

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CROSS-EXAMINATION BY MS. JACKMAN:

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Q. Doctor, I could not be here
this morning, so if I am covering something that
someone covered this morning, please tell me.

I wanted to go first to Baby Belanger.
He is a child who I believe you had exhumed tissue
only in terms of your assessment of his case, and
Baby Belanger was one of the children who was not
supposed to be on digoxin.

It is my understanding that digoxin



I.5 1
2 was found in the tissues after exhumation. Doctor,
3 am I right in saying that because digoxin was found
4 in the tissues, it would be unlikely that the dose
5 could have been given to that child within an hour of
6 death because that would not have allowed for --
7 had it been given within an hour it would not have
8 had time to distribute?

9 A. Well, there probably is some
10 distribution within an hour, but it is hard to
11 predict in a given patient to what degree, and the
12 concentrations, of course, achieved would depend on
13 the dose. It is hard, as I said, to quantitate the
14 concentrations in the liver. I think we have to
15 say that some distribution did take place in this
16 child. To what degree, we do not know because we
17 do not have enough information to speculate about
18 that.

19 But I think that it is unlikely that
20 the dose was given much less than an hour because
21 there is some digoxin in the skeletal muscle and
22 in the liver. There are so many uncertainties in
23 this patient because of lack of information that
24 it is difficult to be very specific about that.

25 Q. Now, Doctor, the next child
that I just want to ask you a few questions about



I.6
1
2 is the Hines child. I wanted to refer you to
3 Exhibit 272, which is your ratings. The number is
4 02057.

5 On page 3 of that little three page
6 brief of yours you stated that you were unable to
7 speculate as to the route, dose and timing of
8 administration, and under "Other Comments" you stated
9 that:

10 "The sole basis for postulating digoxin
11 as a cause of death is the presence
12 of digoxin in post mortem tissues in
13 an infant who was not receiving digoxin."

14 Doctor, had there not been digoxin in the tissues,
15 you would not have had the same concerns about this
16 child?

17 A. I do not think so.

18 Q. So, Doctor, is it fair to say
19 that that statement accurately reflects your views
20 on what could have happened to the Hines child, that
21 if it were not for the digoxin tissues you would not
22 be making any kind of statement as to cause of death?

23 A. I probably would have rated
24 him in the CDC rankings, I probably would have rated
25 him, I suspect, a 1 or I would have had to have
ranked him a 1 had he not had digoxin in post mortem



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exhumed tissues under my own criteria.

Q. Now, Doctor, in reviewing those little reports of yours in Exhibit 272 there are six children where there have been times estimated as to when dose was given.

A. Are you talking about the CDC reports now?

Q. I am talking about Exhibit 272, which is the ratings that you did for the CDC reports.

A. The ratings, okay.

Q. Now, in going through those, I will just list them for you rather than go through each one.

There are six identified. One is Miller and the number is 02065, and they have noted on page 2 of your digoxin summary that the time of death or the time of dose given would have been 2:30. Now, that is -- let me just find it.

A. If you can give me the names I can pull my copies of the scoring sheets.

THE COMMISSIONER: Where are you getting this information from?

MS. JACKMAN: It is in Exhibit 272.

THE COMMISSIONER: Well, 272 is ---

MS. JACKMAN: No, wait a minute.



1

2

Sorry, it is Exhibit ---

3

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THE COMMISSIONER: Is this the
Atlanta Report we are referring to?

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MS. JACKMAN: Exhibit 272, that is
what I have.

7

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THE COMMISSIONER: Well, Exhibit 272,
Dr. Kauffman's material, is that what you mean?

9

MS. JACKMAN: Yes, that is it.

10

THE COMMISSIONER: What are you
saying?

11

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MS. JACKMAN: Now, if you look at
02065, which is near the end ---

13

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THE COMMISSIONER: Yes, which is
Miller.

15

MS. JACKMAN: The Miller child.

16

THE COMMISSIONER: It is the last
one, that is Tab 38.

17

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MS. JACKMAN: That is the Miller
child.

19

THE COMMISSIONER: Yes.

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MS. JACKMAN: On page 2 at the
bottom, the last question it says:

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23

24

25

"Question: Are there other medications
which may have modified response to
digoxin?"



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"Answer: No."

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Then below that ---

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THE COMMISSIONER: This list

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that you are going to supply us is a list of what?

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MS. JACKMAN: The times that have

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been written in the side margin.

8

THE COMMISSIONER: I see.

9

MS. JACKMAN: It has got 81/3/21,

10

so it is March 21st, 1981, and then No. 28 it has
a time, 2:30.

11

THE COMMISSIONER: Well, that is the

12

date of death, is it not?

13

MS. JACKMAN: Q. And Doctor, it is

14

my understanding that that 2:30 is the estimated

15

time that the dose was given; is that correct?

16

A. That was an estimate made by

17

a CDC staffer based on my comments on the next page

18

in which I said that high post mortem level, low

19

tissue levels are consistent with a large IV dose

shortly, 32 to 60 minutes prior to death.

20

Q. Yes.

21

A. I did not put that coding in.

22

Q. Yes, I understood that,

23

Doctor.

24

A. But that was a staffer's

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2 interpretation of my comments so that they could put
3 it on the computer.

4 Q. And Doctor, that has been
5 done with six children?

6 A. Okay.

7 Q. Miller is one of them.

8 MS. CRONK: Excuse me, sir, I do not
9 like to interrupt my friend, but just perhaps hope-
10 fully to be of some assistance, my friend is quite
11 correct, indeed, the statement is made in the expur-
12 gated version of the Atlanta Report that in six
cases a time estimate was made by the Doctor.

13 It was my intention to come to this
14 in re-examination because on the basis of what the
15 Doctor himself has said in his Comment section, it
16 is not fixed. On the basis of what the authors of
17 the Atlanta Report appear to have done with this
18 information, it is 6, and I just draw that to my
19 friend's attention because in fact if you take a
20 look at each of the coding sheets completed by
21 Dr. Kauffman, in two cases, Inwood and Hines, he
22 was not able to make any of the time estimates and
the number appears to be wrong in the Atlanta Report.

23 THE COMMISSIONER: Yes, all right.
24 Thank you. Anyway, we have got Miller at 0230 and
25



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what else have we got now?

3

MS. JACKMAN: Yes, the next

4

one is Cook, Justin Cook and the number is 02064;

5

the estimated time of dose is 2:45, March 22nd, 1981.

6

THE COMMISSIONER: Sorry, I just

7

do not understand. You say 02064. Yes, just give

8

us the names and the numbers and we will take your

9

word for it. Cook is what?

10

MS. JACKMAN: Cook is 02064 and

the estimated time is 2:45.

11

THE COMMISSIONER: 2:45, just give

12

us the time; is that not all you want?

13

MS. JACKMAN: Yes, the next one is

14

Pacsai. The number is 02060.

15

THE COMMISSIONER: Just give us the

time.

16

MS. JACKMAN: Q. The estimated

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time is 1557. Estrella, 02044, estimated time is

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0222; Belanger, 0243, estimated time is 1516; and

19

Lombardo, 02040, estimated time 0250.

20

Now, Doctor, the reason I raise this

21

is I wanted to ask you if you would place any

22

reliance on those times that had been picked as

23

a result of your comments on those particular six

24

children, and the reason I raise that is because with

25



1
2 Justin Cook, Mr. Strathy I believe cross-examined
3 you about the time that the dose could have been given,
4 and there was a fairly broad range. In reviewing
5 the Miller child as well, it seems to me that you
6 have estimated a range that could span -- well,
7 actually, you have given several different times,
8 but the outside range, putting it altogether, the
9 Miller child went into arrest at 2:40 and died at
10 3:27. Your time range, the outside range would be
11 anywhere from 12:15 to 3:12, and the people at the
12 Atlanta Report, the staffer picked 2:30 as the
13 estimated time of dose given.

14 So, Doctor, based on the ranges that
15 you have given already in testimony, is it fair to
16 say that those times that have been picked are just
17 guesses?

18 A. Well, I think I would have to
19 respond to each one individually, because my
20 comments were different in each case and you have to
21 remember they were informal comments that I hand-
22 pencilled at the time. They really were not intended
23 at the time for public consumption.

24 But I would have to respond to each
25 one of these, and in the case of Miller, what they
apparently have done is take a time which is within



1
2 the range that I defined in my comments, and the
3 only problem I had with that is that I do not think
4 we can be that specific and that is why I give a
5 range in that particular case.

6 If we look at Cook, I have discussed
7 in great detail in previous testimony the problems
8 with defining the window for Cook, but I think that
9 most of my testimony, if not all, has consistently
10 placed it somewhere within a 1 to 3 hour window.
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Q Yes, I believe that is correct.

A And I said in my comments here that digoxin was likely administered within one hour of the onset of terminal symptoms, which is consistent with my other comments, and I said although this is speculative. Now, the staffers used one hour it looks like for their purposes for coding.

Q Yes.

A So, again, the only problem I have with that is that if you are going to put numbers in a computer you have to put a specific number but I don't think that I could be that definitive to say that I think that the digoxin was given at 2:45. I had to give a range in which I thought it was most probable.

Q Doctor, is that why you didn't fill out those spaces on page 2 of your report?

A You know, I frankly don't remember why I didn't fill them out. I don't remember seeing that question at the bottom of the report or responding it to it when I filled them out. I think I said that before. The copies that I have do not have that question on them. I have the coded numbers but not the question.

Q Doctor, if you had your own



J.2

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way, would you have preferred not to have limited it
or focussed on a particular time?

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A. Well, I think in the majority
of these cases it is difficult. I had to either
say I couldn't give a window or I had to give a
range or I had to give a very broad time possibility.
I think it is difficult for me at least to pin it
down to a specific time.

9

10

Q. So, presumably, Doctor, it would
be difficult really for anyone else to do it too?

11

12

13

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15

A. Well, they will have to answer
for themselves. I think they were trying to use my
comments to provide a cutoff number, but even the
range I give is somewhat speculative in a lot of
these kids and when you pin it down to a specific
time it is even more or even less certain.

16

17

Q. Doctor, I wanted to try and
avoid going through all six children.

18

19

20

21

A. Okay.
Q. Because of the time limitations.
Is it fair to say that all of these comments apply
to all of the six children?

22

23

24

25

A. I hate to generalize it. In
some of my cases my comments really didn't give a
finite time frame and I don't know how they arrived



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at their particular coding number.

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Q. Yes, Doctor. That was true of
Kevin Pacsai?

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A. In some of the others I did
give a finite time frame and they selected something
within that time frame, which is the only way you
could do it if you are going to pick one number. As
I say, I don't have any problems with that except I
don't think we ought to get hung up on a specific
time being more probable than any other time within
the time frame that I gave.

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Q. Okay. Then, Doctor, I will move
on to something else.

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Doctor, with the Inwood child I
believe it was, or maybe it was Pacsai. In any event,
Mr. Scott was examining you on December 1st, it is
Volume 73 at page 6212, and this was about potassium
levels. Actually, I have in my notes I think it was
reference to the Inwood child but I think it is with
reference to Pacsai. You can't tell from the trans-
cript.

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MR. LABOW: It is Pacsai.

MS. CRONK: Which page number?

MS. JACKMAN: It was page 6212 and it
was with reference to the Pacsai child.



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Now, Doctor, part way down that page you gave an answer about a question Mr. Scott put to you about digoxin toxicity and it is your answer that I am interested in. You stated:

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"My comment to that would be that it is true that an abnormally low potassium level will predispose an individual to toxicity from a smaller amount of digoxin.

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"I am not sure I would agree that reducing an abnormally elevated potassium concentration to a normal concentration would increase toxicity."

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The reason I raise that, Doctor, I wanted to draw your attention to Exhibit 17 which I also raised with Dr. Hastreiter last week. It is an article by Dr. Doherty on how and when to use digitalis serum levels. Could someone give the doctor a copy. Could the doctor have a copy of that exhibit? It is Exhibit 17, I'm sorry.

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Now, Mr. Commissioner, we had this problem last week, I believe it is your page 2 and I am referring to my page 3.

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THE COMMISSIONER: Oh, yes, all right. We may have fixed that up.



J.5

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2 MS. JACKMAN: Q Doctor, on the last
3 page of that article in the second column, it is
4 the third last paragraph, Dr. Doherty I understand is
5 a doctor that has had some experience with digoxin,
6 that is what Dr. Hastreiter told us. But he states
7 in the bottom part of that third last paragraph in
8 the second column that, he states:

9 "However, a high serum potassium
10 level affords some protection against
11 digitalis intoxication and may give
12 rise to a high digoxin serum level
13 without clinical evidence of
14 digitalis intoxication. In patients
15 who are dialyzed in this state a
16 toxic reaction develops as the
17 serum potassium value falls towards
18 normal levels."

19 So, Doctor ---

20 THE COMMISSIONER: Miss Jackman, we
21 have had this before. You put the same question to
22 him. My note is to the effect he found that
23 proposition was not one that appealed to him.

24 MS. JACKMAN: It didn't appeal to
25 Dr. Hastreiter.

THE COMMISSIONER: Was it Dr. Hastreiter



J.6

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that was asked that question?

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MS. JACKMAN: Yes.

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THE COMMISSIONER: Oh, I see, all right.

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MS. JACKMAN: Q. I was asking Dr.

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Hastreiter about the high digoxin, the digoxin levels increasing with respect to potassium and what I would like to refer Dr. Kauffman to is in light of the comments he made that Dr. Doherty states that a toxic reaction could develop - actually, he states it does develop as the serum potassium value falls towards normal levels.

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So, Doctor, do you believe that that could be possible?

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A. I'm not certain. There is a fair amount of controversy in the literature now as to how serum potassium concentrations interact with digoxin intoxication because this is very important as to how you treat digoxin intoxication with potassium, should you give potassium in the presence of digoxin intoxication even though the potassium concentration may be normal in serum or even a little high. Some authorities feel that you should not give additional potassium when the potassium is normal or high; some feel that even in the presence of an elevated potassium in the presence of digoxin



J.7

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2 intoxication that you should give additional
3 potassium because it may be protective against the
4 effects of digoxin. So, there appears to be contro-
5 versy in that.

6 My own opinion at this point in time,
7 and it is subject to change with more definitive
8 information, is that lowering an extracellular
9 potassium concentration, which is the serum
10 concentration, in the presence of digoxin intoxication
11 from a markedly elevated level to a normal level, is
12 unlikely to exacerbate digoxin intoxication but it
13 could I suppose do it. I don't think it has been
14 well documented yet. It is a possibility but I don't
15 think it has been well documented. But there is no
16 doubt in my mind that an abnormally low potassium
17 extracellular potassium contributes or increases
18 digoxin intoxication.

19 Q. Now, Doctor, with Kevin Pacsai
20 there was some evidence last week that he may have
21 had what is called an atrial flutter and that could
22 have an effect on digoxin levels as well.
23 Dr. Hastreiter talked about that when I examined him
24 on it.

25 In Dr. Doherty's article he also
mentions that atrial flutter could have an effect on



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digoxin levels. What I am wondering is, is it possible that given that he may have had a tolerance to higher digoxin levels when the doctor, I believe it was Dr. Costigan, made efforts to reduce the potassium level, that, in conjunction with the atrial flutter, could have resulted in digoxin toxicity?

A. Well, let me correct your comments about the atrial fibrillation or atrial flutter in relation to digoxin.

Q. Yes.

A. What the paper here says and what my understanding is is that patients who have atrial fibrillation require higher concentrations of digoxin to reduce the tachycardia that is associated with atrial fibrillation or to convert them to sinus rhythm. You don't always get them converted but at least you can slow the ventricular rate to where the cardiac output is maintained.

Q. So, they could tolerate a higher level?

A. It takes a higher concentration to do the job in atrial fibrillation than it does treating another kind of heart disease where they are simply in failure with a normal rhythm. That is all this is saying here.



J.9

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Q. Yes.

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A. That doesn't say that atrial fibrillation causes a high digoxin concentration.

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Q. No, I understand that, but it is my understanding that the child could tolerate a higher digoxin level without a toxic reaction if the child had an atrial flutter?

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A. Well, I don't think that that is what is being said here and I don't think that that is true necessarily either. What I think is being said here, and it is my understanding, is that atrial fibrillation or flutter requires a higher concentration to digitalize a patient and produce the effect that you want.

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Q. Right, without a toxic reaction?

A. Well, it may or may not be

without any toxicity but it requires a higher concentration to do the job. You usually try to maintain a higher concentration in the serum when you are treating a patient, all other things being equal, in a patient who you are treating for atrial fibrillation than you do in another patient who has congestive failure for another reason.

Q. All right. So, my question,

Doctor, is, given that Kevin Pacsai may have had an



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atrial arrhythmia, when Dr. Costigan made efforts to reduce his potassium levels, which he did, and that is referred to in the evidence that I just gave you previously, that that could have resulted in a toxicity, a toxic reaction?

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A. That's difficult to say. He had so many problems from his inherent arrhythmia that it is difficult to speculate on that.

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Q. But as a hypothesis it is possible?

A. That is a hypothesis, I don't

know what to do with it. I don't find it as appealing as blaming it on his inherent heart disease and an extra amount of digoxin. You are suggesting that a therapeutic amount of digoxin became toxic when his potassium was reduced?

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Q. Yes.

A. Do I understand you correctly?

Q. Yes, I am putting that as a

hypothesis, as something that could be possible. I am not saying that it is right now.

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A. No, but I want to make sure that I understand your hypothesis, that the hypothesis includes that he had his inherent heart disease with the paroxysmal atrial tachycardia.

Q. Right.



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A. That he received a therapeutic amount of digoxin and that his potassium was lowered to a more normal, or attempts were made to lower it and that that made him digitalis toxic with a normal amount of digoxin being present.

Q. Than it could have, yes.

A. Yes. In my opinion that is a very unlikely scenario.

Q. But it is one that is possible?

A. Well, anything is possible in the universe but I think it is very unlikely.

THE COMMISSIONER: Dr. Costigan will be glad to hear that.

THE WITNESS: Pardon?

THE COMMISSIONER: Dr. Costigan will be glad to hear that because he was very concerned when the child died that he might have done just that and that is what started the investigation.

THE WITNESS: Yes. Any time you have a child with that kind of an arrhythmia and digitalis on board, you know, a number of things can trigger a fatal arrhythmia.

MS. JACKMAN: Q. Yes. Doctor, I actually just have one more thing to cover.

Exhibit 266 is your report to the



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Crown Attorney. Now, on page 2 of that report ---

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A. Is this the first ---

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Q. This is the letter or I guess
the opening statement to the report.

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A. Dated 16th of December, 1982?

6

Q. Yes.

7

A. Okay.

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Q. Well, no, actually it is not
dated.

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A. It is on the final page, I signed
and dated it. At the bottom of page 15 of that report
there should be a date, 16/12/82 and my signature.

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Q. Yes. Okay, on page 82 of that
first report, in the very last paragraph you stated
with respect to preserved autopsy tissue that:

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"Such assays may be helpful as
supporting evidence if they are so
high or so low as to be inconsistent
with the rest of the available
information."

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Now, Doctor, the reason I am raising
that is because in looking at the letter that you have
written, or, sorry, Appendix 3 to the Atlanta Report -
Appendix 1, excuse me, to the Atlanta Report which
states that:



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"It is criteria used by

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consultant pharmacologists to assess

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digoxin findings taken verbatim from

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his report."

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THE COMMISSIONER: I am sorry, I am

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going to have to find that. Your Atlanta Report is

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not numbered, I take it?

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MS. JACKMAN: No.

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MS. CRONK: To assist you, sir, the

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Appendix 1 that my friend is referring to is in its

12

entirety the letter written by Dr. Kauffman to Dr.

13

Smith which forms Tab 1 of the CDC materials. Except

for the salutation paragraph it is the same letter.

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THE COMMISSIONER: All right, thank you.

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What page then?

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MS. CRONK: It is under Tab 1 of the
bound Atlanta Report.

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THE COMMISSIONER: Yes. What page
were you at of that letter?

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MS. JACKMAN: The Appendix 1, or
the letter?

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THE COMMISSIONER: Well it is the
same thing apparently, so which page?

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MS. JACKMAN: Oh, I'm sorry, page 2.

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THE COMMISSIONER: Thank you.

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MS. JACKMAN: Q. Actually, Doctor,
that was my next point, was to point to that letter
of December 14th, 1982 to Mr. Smith.

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Doctor, the reason I drew your
attention to Exhibit 266 and that statement, is
because it appears to me that the wording in Exhibit
266 is pretty well the same as what appears in the
letter to Smith and in the Appendix 1 of the Atlanta
Report, except for that sentence. In both of those
reports you have left out that one sentence:

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"That such assays might be helpful as
supporting evidence if they are so
high or so low as to be inconsistent
with the rest of the available
information."



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Doctor, I wondered why you left that sentence out of the other two reports when basically the wording is ---

A. Which other two reports?

Q. The other two letters, Appendix 1 to the Atlanta Report.

A. Yes.

THE COMMISSIONER: Which one, it is in, I take it it is in Exhibit 266 and it is not in the Atlanta Report or in the letter to Dr. Smith, is that right?

MS. JACKMAN: Yes, that is correct.

THE WITNESS: The Atlanta Report is the same as the letter to Smith, there are only two documents that we are talking about I think.

MS. JACKMAN: Q. Yes, and in this letter that I have referred you to, this report in Exhibit 266 to Jerome Wiley is pretty well the same as well. The wording, all the paragraphs are the same except that one sentence is left out of the other two and it is included in this, and I was just wondering if that was done deliberately or why that sentence was left out of the other two letters?

A. I don't think there is any



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2 significance to omitting it, frankly, I don't know
3 why it was left out.

4 Q. You don't recall?

5 A. I essentially used the same
6 notes to dictate both letters and I don't know that
7 there is any significance to me having left it out
8 of the letter to Dr. Smith. I don't recall that
9 there was any significant reason to do it and I
10 don't attach any significance to it now.

11 MS. JACKMAN: That is it.

12 THE COMMISSIONER: Fine, we will
13 have our full hour and a half because I think - oh,
14 do you have something you wanted to say?

15 MR. BROWN: You might well chastise
16 me. In reading Dr. Kauffman's evidence I notice
17 Miss Cronk dealt with a couple of the babies, and
18 one of them was Velasquez, and I think she asked
19 Dr. Kauffman why he placed Velasquez in that category.

20 In reviewing the Atlanta Report
21 subsequently I noticed that there was a comment
22 attributed to Dr. Kauffman that stated that he doubted
23 whether there was a causal relationship between
24 Naloxone and the death of that infant, and I don't
25 think that had been raised previously.

THE COMMISSIONER: All right, do you



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want to just ask that question now? Where is it,
what page in the Atlanta Report?

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MR. BROWN: It is in the summaries
of the children, in Appendix 2, it is the 61st page
the way I bound it, but there is no guarantee that
is the number in your report, sir.

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THE COMMISSIONER: What is the
number for Velasquez?

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MR. BROWN: The child's number is
02011.

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MS. CRONK: Tab 13, sir.

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THE COMMISSIONER: Tab 13, but it
is, in the Atlanta Report, my copy at page 54, yes,
it is the West Indies boy, Tab what did you say?

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MS. CRONK: 13, sir.

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THE COMMISSIONER: And what is your
problem?

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MR. BROWN: It is simply that at
the bottom of the case history there was a sentence
which reads:

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"The impression of the consultant
pharmacologist was that a causal
relationship between Naloxone and
death was unlikely."

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And the role that that drug has.

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THE COMMISSIONER: That is exactly
what he said, isn't that exactly what he said?

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MR. BROWN: In the scoring sheets.

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THE COMMISSIONER: No, no, he says
causal relationship with Naloxone appears questionable
to me.

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MR. BROWN: Yes. All I'm saying
is I don't think that point has been put to him
before and I was wondering whether he could simply
explain why.

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THE COMMISSIONER: Yes, all right.
I don't know whether it has or not, but would you
like to ---

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THE WITNESS: I don't recall discuss-
ing it earlier.

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THE COMMISSIONER: No, all right.

THE WITNESS: Well, Naloxone is a
drug which is called a pure opiate antagonist. What
that means is it binds to the opiate receptor but
it doesn't produce any effect and it inhibits the
binding of other drugs or substances in the body
that might otherwise bind to that receptor.

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Naloxone because of that produces
very little, if any, detectable acute effect when
people receive it. In fact there have been case



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2 reports of Naloxone being administered in doses at
3 tenfold apporoximately of the recommended dose and
4 no effects either ill or otherwise being documented
5 in the patients. So it is highly unlikely in my
6 estimation that Naloxone would produce a sudden
7 catastrophic event which would be associated with
8 death.

9 There is some recent information that
10 suggests that Naloxone may in some way, may modify
11 in some way the effects of endogenous substances
12 called endorphins or enkephalin, and theoretically
13 it is conceivable that its interference with the
14 functioning of these compounds in the body could
15 produce an effect, although this has not been
16 readily measured, has not been measured. So taking -
17 the other piece of information is that I am not
18 aware of any reports of idiosyncratic reactions
19 to Naloxone causing sudden death. So taking all
20 that into consideration I thought that it was highly
21 unlikely that Naloxone was related to this infant's
22 problem, or to this infant's death.

23 THE COMMISSIONER: Yes, all right.
24 Thank you. Is that it, Mr. Brown?

25 MR. BROWN: There was one question
that Mr. Strathy I think put to Dr. Bain when he



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2 testified, and he asked Dr. Bain to assume that there
3 was the presence of digoxin, and was Dr. Bain aware
4 of any reports in the literature and whether Naloxone
5 would play a role in that circumstance. I was
6 wondering whether the Doctor could address the same
7 question, that is assuming digoxin was present in
8 the child, are you aware of any reports in the
9 literature which suggests that Naloxone might have
10 a unique or adverse reaction?

11 THE WITNESS: In the presence of
12 digoxin?

13 MR. BROWN: That is correct.

14 THE WITNESS: No, I am not aware of
15 any reports of drug interactions between those two
16 drugs.

17 THE COMMISSIONER: Yes, all right.
18 We will recess until 2:15, and Miss Cecchetto, in
19 case Mr. Shanahan does not appear will you be prepared
20 to be here so we can start at that time?

21 MS. CECCHETTO: Yes.

22 THE COMMISSIONER: All right, until
23 2:15.

24 ---Luncheon recess.
25



AA/DM/ak

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2 ---Upon resuming at 2:15 p.m.

3 THE COMMISSIONER: I don't see any sign
4 of Mr. Shanahan so, Miss Cecchetto, would you proceed.

5 MS. CECCHETTO: Yes, Mr. Commissioner.

6 RE-EXAMINATION BY MS. CECCHETTO:

7 Q. Dr. Kauffman, I would like to
8 clear up an area that is somewhat confusing for me.

9 THE COMMISSIONER: Before I forget,
10 I take it - what about Mr. Young? I had not thought
11 of that, but he is not here either. Well, he may
12 consider he is entitled, however, if he is he can
13 come in after you. Yes.

14 MS. CECCHETTO: Q. Well, the area
15 of confusion that I had was brought up by Mr. Strathy
16 in his cross-examination and it dealt with the timing
17 of administration in respect of Justin Cook. I
18 would ask you to go to Volume 73, Doctor, at page
19 6045, approximately line 15. Mr. Strathy has asked
20 you to assume the administration of one adult ampule
21 of digoxin intravenously; and at approximately line
22 14 he asked this question:

23 "Q. So you say that your one adult
24 ampule theory --

25 A. At 3:30 it became even less
likely with the times that we were



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3 "corrected about.

4 Q. But it becomes more likely
5 if it is administered closer to death?

6 A. If it was given just before
7 circulation stopped, moments before
8 circulation stopped, then I would
9 accept it, yes.

10 Q. Let me put to you this. Would
11 you be prepared to accept one adult
12 ampule, I gather you would, at or
13 very near the time the circulation
14 stopped?

15 A. I think so, yes."

16 Now, Doctor, I had asked you whether
17 or not you could accept one adult ampule at or near
18 the time circulation stopped, or in Mr. Strathy's
19 words, moments before circulation stopped, whether
20 you could accept that that would account for both
21 the serum and the tissue levels in Justin Cook?

22 A. I think I was thinking at
23 the time I gave these answers, I was thinking in
24 terms of the serum concentration and I think that
25 my answers were predicated on that alone. I
indicated other times and I do so now, that I cannot
reconcile the serum and tissue concentrations with



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administration of a dose of that - just before
circulation stopped. I can't accept that that dose
would produce both the serum concentration and the
fresh tissue concentrations that were observed in
this patient if administered in that time frame.

Q. Could any amount of an IV
bolus at or about the time circulation stopped
account for both the serum and tissue levels in
Cook?

A. I think it is very difficult
to account for it that way because an IV bolus of
the size to produce that degree of tissue concentra-
tion would have to produce a much, much larger serum
concentration than what was observed. So if you
postulate a dose just before circulation stopped of
the magnitude to produce that tissue concentration,
I don't think then you can reconcile the serum
concentration of only 70, because we are really
dealing for all intents and purposes of putting the
dose into the central compartment with very, very
little distribution.

Q. Now, Doctor, just to be clear,
because there was some confusion; keeping in mind
these times that Justin Cook appeared to experience
difficulties at 3:45 and I am referring to his



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2 medical chart now which is Exhibit 116, pages 29 and
3 30.

4 A. I don't know if I have that,
5 no, I don't; which page?

6 Q. Page 29 and 30.

7 A. Okay.

8 Q. There is an indication in
9 Nurse Nelles' note at page 25 that he began to
10 experience difficulties at 3:45. Then we have an
11 indication that the cardiac arrest was called, or
12 the Code 25 was called at 4:20. At page 30 there is
13 an indication that the sample was drawn at 4:30,
14 the serum sample, and resuscitation continued and
15 the child was pronounced dead at 4:56.

16 Now, keeping in mind those times,
17 Doctor, can I ask you for your best conclusion with
18 respect to the timing of death if your hypothesis
19 is the administration of one adult ampule of digoxin?
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A. I am not sure I follow your question. You are asking me when would I postulate the timing of death?

Q. The timing of administration?

A. Of administration.

Q. If you're positing one adult ampule of digoxin, what would you conclude would be the best timing to account for both the serum and the tissue levels in Cook, or ---

A. Well, again, I have a difficult time postulating one adult ampule, which would be .5 milligrams of digoxin, to explain both of these. The reason is if you give it just before death, however we want to define that, so that there is limited or no distribution, then I cannot explain the tissue concentrations.

If we move it away from death far enough that I might be able to accept the tissue concentrations, then that size dose could not explain the serum and the tissue concentrations because it takes a larger dose to produce a concentration because some distribution has taken place. So the one ampule hypothesis that has been put to me previously is difficult for me to accept no matter which scenario you build it into. I do not know if



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I have answered your question or not.

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Q. Well, what would you postulate, what type of dosage would you postulate, Doctor, on those facts?

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A. Well, it is difficult for me and that is why I never did it earlier. What I did do was I estimated a minimum dose, assuming no distribution because I have some data in the literature to tell me what the central compartment is in a baby this age. That assumes no distribution, and I postulate a minimum dose based on that assumption. Then I said I do not think this is likely because I cannot use that to explain the tissue concentration. Then I estimated a maximum dose based on full distribution, and a volume of distribution of 10 litres per kilogram, which I do not think either represents the actual event. Then I said it had to occur some time beyond the time for no distribution and some time before total distribution would have occurred.

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Now, my problem with trying to estimate a dose which could have been given somewhere between those two extremes is that I do not know in this baby how rapidly distribution occurred, and without knowing that, why, I really cannot come up with a dose other than to say it was something larger than the minimum



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dose I calculated and something smaller than the
maximum dose I calculated.

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Q. And your minimum dose, I under-
stood, was one ampule with no distribution?

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A. Yes, well, it was somewhere in
that neighbourhood, you know, about .5 milligrams, it
was roughly .5 milligrams. But I did not and I still
do not think that that can explain the tissue
concentrations.

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Q. Now, staying with Baby Cook for
the moment and turning to the cross-examination of
Ms. Symes, and this is at Volume 74, Doctor, page 6363
and this continues on to about page 6375, I am not
going to read it to you but my friends can correct
me if I am wrong on this, but Ms. Symes, in those
pages, put to you a scenario about the possibility
of medication error and the scenario that she put to
you was she asked you to assume a medication error
whereby digoxin was substituted for propranolol or
Inderal. She asked you to assume in those pages the
scenario whereby a person who was intending to draw
up .5 millilitres of propranolol or Inderal would
normally draw up a whole vial, but instead of drawing
up the Inderal, mistakenly drew up a vial of digoxin.
She asked you to assume that the person would draw



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up the whole vial of digoxin, which I understood to be 2.2 millilitres or double the volume?

A. No, 2 millilitres.

Q 2 millilitres. She then asked you to assume that that would be taped to the bed, as I understand it, and she asked you to assume administration from a syringe, and she further asked you to assume that the person who was administering from the syringe would simply give half of what was in the syringe without checking the amount that was in the syringe.

In effect, Doctor, because there was some confusion, she asked you to postulate two errors, as I understand it. She asked you to postulate in her scenario the drawing up first of the wrong medication, and secondly, the subsequent administration of the wrong amount.

Now, I ask you, Doctor, what do you consider to be the probability of this dual type error occurring in a hospital situation?

A. Well, I can accept in general, not these two medications, but I can accept in general the possibility of one medication being substituted for the other one, particularly if the vials and the labelling on the vials are very similar.



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In this particular case, when I was presented the vials, as I recall, they were quite different in appearance and size and colour and labelling and so forth. So I thought that that was an unlikely mistake to be made. I think it is even more unlikely that twice as much material would be drawn up without it being detected by at least the two people that we are postulating would have had to handle this, one who drew it up and one who administered it. I think it is unlikely that one or the other would not have detected the fact that twice the volume existed or that they would not have noticed the graduations on the syringe and realized the volume that they were injecting.

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In fact, it could be possible that it would even require a different sized syringe than one would ordinarily use to draw up the propranolol.

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Q. All right. Now, Doctor, keeping with that scenario and assuming for the moment that that is exactly what happened, can I ask you to comment on the level of competence of those two individuals if such an error existed?

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A. Well, I ---

Q. Perhaps I can put it this way:

if you were the administrator of a hospital, how



BB.6

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would you feel about keeping those people on in your
employ?

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A. Well, I think I would be very
unhappy if I was a physician to whose patient that
occurred. I think it is very incompetent. I think
that a combination of not looking at the graduations
on the syringe and not knowing how much you injected
is somewhat negligent, but it may occur sometimes.

Q. Now, Doctor, moving from this
scenario to the case of Justin Cook, doesn't this
error scenario become even more unlikely when one
considers that there were two separate administrations
of propranolol to Justin Cook in the amounts of .2
and .4, so would you not need an additional error?

A. I think in Cook the propranolol
was administered on two separate times, as I understand,
was drawn up in two separate syringes and was given
a few minutes apart during that time. So if we are
postulating this type of error, that type of error,
compound error, would have had to occur with two
separate syringes, I suspect, and to me that seems
highly unlikely that it could occur without being
detected by one of the individuals involved, unless
they were totally not paying attention to what they
were doing.



BB.7

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Q And to just wrap up this

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scenario ---

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THE COMMISSIONER: The propranolol, this was not left by the -- was this the one left by the bed in the syringe?

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MS. CECCHETTO: Yes, it was.

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THE COMMISSIONER: If it was left in the syringe, was it the total amount for the two applications or just the total amount for the one? I have forgotten how much was left.

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MS. CECCHETTO: I think there is some question as to whether it was administered from one syringe or two syringes. Ms. Cronk perhaps can ---

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MS. CRONK: I was starting to rise on exactly that point, sir. That has not yet been clarified before you.

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The evidence certainly is to date that at least there was one syringe taped to the bed. The amount of the drug contained in that syringe has not been established.

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THE COMMISSIONER: But if half of the amount were given at one time and half of it were given at another time, that does not take two errors; that just takes one error.

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THE WITNESS: That is correct. If

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BB.8

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2 both of those two doses that were given within 10
3 minutes of each other were given from the same syringe,
4 then it would be a dual error in drawing up the
5 medication, the wrong medication and the wrong amount,
6 and an error in the amount that was actually
7 delivered to the patient. It would not involve a
8 dual error in the sense that it had been drawn up
9 inaccurately in two separate syringes. I do not
know which situation applies.

10 It seems unlikely to me that this
11 kind of thing could occur and that it could explain
12 the events which ensued.

13 MS. CECCHETTO: Q. Well, Doctor, just
14 to wrap up that scenario, doesn't this become even
15 more improbable when one considers the evidence of
16 Dr. Kantak that the vial of Inderal was taped beside
17 the syringe? Doesn't that really throw out this
18 whole scenario if that is the case, and I know Ms.
19 Symes indicated the other day there may be further
20 evidence, but if the vial of Inderal was taped beside
the syringe, doesn't that throw out the scenario
completely?

21 A. Well, if indeed a vial with
22 Inderal labelling was taped to that syringe, then I
23 think it is extremely unlikely that that syringe
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BB.9

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contained digoxin unless somebody deliberately mis-
labelled it.

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Q. Now, Doctor, we have heard a
lot about medication error and the frequency of
medication errors in hospitals, and you were examined
this morning by Ms. Symes on medication errors. Can
I ask you to comment how often medication errors in
hospitals result in death; is that as common as
medication error?

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A. No, it is not as common as
medication error, fortunately. I cannot give you
specific numbers or percentages, but I can tell you
that the great majority of errors that are detected
are of little or no significance to the patient in
terms of causing ill effects to the patient, certainly
not death. Death must occur with very, very small
percentage of the medication errors that are made,
I would guess under 1 per cent. But I do not know
the exact numbers.

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Q. We have heard a lot about
medication error going undetected. Doctor, where
death ensues, is it not very often the case that
the medication error is discovered? Is there not
an investigation and is it not often the case that
a medication error is discovered as the cause of



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death where that occurs?

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A. Well, I suppose sometimes it is, but I can think of possibilities of scenarios where it might not be discovered, where the death was not totally unexpected and the error was not detected and that it goes undetected. I would expect, though, that if the death is unexpected, that that would result in an investigation of what went on around the death and that the medication error would be detected. I think it would depend to some degree on how unexpected the death was and how alert the caretakers were to the possibility of the medication error at that point in time.

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THE COMMISSIONER: But surely, a medication error would be in exactly the same class as digoxin overdose, probably, would it not?

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THE WITNESS: I am sorry?

THE COMMISSIONER: Well, if one can assume or hypothesize, if that is a word, that these children died from a massive overdose of digoxin, now, in March, of course, everybody was getting suspicious, certainly in December or in other months no one was suspicious, no one would expect an error in -- no one would expect digoxin intoxication, no one would expect an error in the medicine, and therefore,



BB.11

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no one would take the appropriate tests, would they?

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THE WITNESS: That is what I meant

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when I said that ---

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THE COMMISSIONER: Because these

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children could have died from their symptoms?

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THE WITNESS: That is what I meant

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when I said I think it depends to a large extent on

9

how unexpected the death might have been. If the

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death was an expected event or not unexpected, at

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least, then one might not even consider that an error

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of any sort might have happened because the death

was not a surprise and may not be picked up.

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THE COMMISSIONER: This is the problem

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with that, at least the problem as I see it, with

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that theory that you are suggesting is if the child's

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death was expected anyway, certainly there would be

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no necessary concern or at least concern, but not

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any suspicion that there would be an error in the

administration of a drug.

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THE WITNESS: Unless there were other reasons to suspect an error at that point in time, it was picked up from other causes. I think death being the index to lead you to the suspicion of the medication error would ordinarily be an unexpected death. A death which was totally consistent with the patient's condition at that point in time would not necessarily bring you to think about a possible medication error. Do you understand what I'm saying?

MS. CECCHETTO: Q. I understand what you are saying but picking up on the Commissioner's question, Doctor, if you were in a hospital situation where there was an increase mortality and especially among the nursing staff if there was an increased concern about this increased level of mortality, do you not think that perhaps they might consider medication error and at least check to see whether or not there was an error indicated in the record? Might that not be an avenue they would pursue?

A. Well, not having been there it is hard to say but I think that that is one thing that would be a legitimate thing to pursue but in an infant ward like this there might be a lot of other things to look at too and that's the admitting



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diagnosis of the babies, the conditions of the babies and any other changes that might have taken place that would result in an increased mortality if indeed you sense an increased mortality at that point in time. Errors in medication could be one thing that people might want to look at but sitting there at that point in time that would be one of a number of things that you would probably want to take into consideration if you perceived an increased in mortality rate at that point in time.

Q. All right. Now, Doctor, Miss Symes at Volume 74, page 6394 refers you to Exhibit 276, which is the case report by Dr. Hastreiter entitled "Accidental Digoxin Overdose in an Infant Post Mortem Tissue Concentration".

Now, in the course of her reference to that article she refers to the child as being a seven week old child. In fact, the child, if one goes to the report, is a one month old child and what happened in this case was that the child erroneously received 2 milligrams of digoxin intravenously and died 45 minutes later. At page 6396 of Volume 74 you indicate that this infant in terms of tissue levels looks like a close twin to Justin Cook.

The question I have for you with



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respect to this case report, Doctor, first of all,
how many adult vials would be required in order to
achieve or to administer 2 milligrams of digoxin?

A. I think it would be 4,
there are 5 milligrams per vial, so, there would be
4.

Q. And this in effect would be
an enormous dose would it not, Doctor?

A. For a child this size it would
be, yes.

Q. And as you pointed out in your
evidence the child was also, Cook was also an older
child and in this case the child in the case report
was chronically digitalized, whereas, Cook was not
on digoxin and should have not received digoxin.

A. That is correct.

Q. I would ask you, Doctor, can
there really be any extrapolation at all from this
case report to the case of Justin Cook?

A. Well, there are a lot of
dissimilarities. The only similarities are really
the serum and the tissue concentrations. The
dissimilarities in disease, in age and in being
digitalized make it difficult to extrapolate directly
and I did not intend to imply that. I was simply



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alluding to the similarities in the serum and the tissue concentrations at the time I made that comment. I think that one might expect in a baby who is chronically digitalized, one would expect a higher tissue concentration with the comparable dose than one might expect in a baby getting a single acute large dose.

MS. CRONK: Sir, I think just to be fair to my friend Miss Symes who wasn't in the room at the time. The article, as Miss Cecchetto suggests, does indicate that the infant was one month old, he was seven weeks old at the time of death.

MS. CECCHETTO: Oh, sorry, I should have read on.

THE WITNESS: I am not sure that makes a difference in any of my answers.

MS. CECCHETTO: I apologize to Miss Symes.

Q. Doctor now, I'm going to turn to the case of Kristin Inwood and one of the areas of concern is at Volume 72, page 5849. This was when you were being questioned by Miss Cronk in respect of the 491 serum level in Kristin Inwood. She was canvassing with you in her questions that the possibility that digoxin had been administered



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2 instead of Lasix, she asked you to assume that that
3 error was made in that the wrong medication was
4 given but that the appropriate dose was given and
5 at page 5849 you conclude that that would take a dose
6 of approximately .75 milligrams of digoxin and it
7 would lead to a 30 nanogram per millilitre level,
8 then - this is the area of concern that I have -
9 assuming this level Miss Cronk then asked you to
10 assume that there is little or no distribution to
11 the tissues and at page 5849 at about line 5 there
12 is the question:

12 "Q. Then can we deal with the
13 latter issue first, Doctor? If we
14 assume that this kind of error was
15 made, achieving a concentration that
16 you have calculated to be 30 nanograms
17 at the most per millilitre, if we
18 take into account first of all a
19 multiplier within a range that is
20 acceptable to you, and if we, for
21 example, suggest that the multiplier
22 in this case was 3 or 4, taking the
23 outside 4, that level could be
24 elevated in known ranges to 120
25 nanograms post mortem. Would that be
correct? "



CC6
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3 And your answer is that that would
4 be correct. And the question continues on with the
5 hypothesis; but Doctor, let me ask you this, if there
6 was no distribution in it at all, would you expect
to see a post mortem multiplier?

7 A. No, I don't think so. I was
8 ignorning in my assumption here, probably mistakenly,
9 but I ignored the implicit assumption that no distri-
10 bution had taken place, I was including in that
11 hypothetical situation - well, it wasn't hypothetical
12 but that situation we were assuming and I have to say
13 that my understanding of the increase in post mortem
14 digoxin levels in the serum is due to release and
15 redistribution of digoxin from tissues that if indeed
16 under the scenario we were describing at that point
17 no distribution has taken place, I haveto say that
18 assuming a multiplier of fourfold is probably not
19 valid, in fact, I would expect to see little if any
20 increase under the conditions we were describing in
21 this scenario. The only redistribution that one
22 might see would be from the red blood cells and that
23 would be minimal. So, I think that is hard, taking
24 my implicit assumptions into account here to agree
25 that the fourfold multiplier would make sense you have
to assume some significant amount of tissue



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distribution to assume a fourfold multiplier and I have to agree with you that if we assume no tissue distribution we really can't assume a fourfold multiplier in going through this calculation.

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Q. What about if you assume a little distribution, can I ask you, Doctor, whether or not you would expect to find the levels that were found in fixed tissue in Inwood, and I tell you that the levels that were found were 230 nanograms in the left ventricle and 300 nanograms in the septum.

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A. I think that is very unlikely.

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Q. Now, continuing on with the reliability of the Inwood sample. Mr. Strathy and Miss Symes both cross-examined you on the reliability and the implication that I took from their cross-examination was the suggestion that the sample was not reliable and was worthless. Would you agree with that, Doctor?

23

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A. No, I never meant to imply that. I could not, even with the reservations that I had about the quality of that sample, I certainly could not ignore it and I took it as an important piece of information when I considered this case.

Q. And Inwood in any event even without that sample was not a case where you were



CC8

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prepared to completely discount digoxin intoxication?

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A. That is correct, even before

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I knew that.

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Q. Okay. Now, Doctor, Mr. Scott

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in his cross-examination asked you about seizures

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and basically the gist of your evidence, and this can

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be found at Volume 73. I'm not going to read from

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it but for my friends in case they want the

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references it is page 6217 to page 6225. You

11

indicated, Doctor, whether or not seizures occurred

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was really not helpful to you in determining whether

13

or not there was digoxin toxicity in these children.

14

A. Yes, I really couldn't make

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any kind of judgment based on seizure incidents.

16

There are a lot of causes for seizures in these

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kinds of patients. It doesn't tell me that there

18

wasn't digoxin intoxication and it doesn't prove

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to me that there was, so, I really didn't view that

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Q. Because, Doctor, you are going

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to go home after your evidence here, if someone

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were to suggest in the future ---

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THE COMMISSIONER: He doesn't have

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to, Miss Cecchetto, if he has some other plans.

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3 MS. CECCHETTO:Q.Well, you can stay
4 on if you like, but if someone were to suggest in
5 the future that convulsions or seizures were
6 inconsistent with digoxin toxicity how would you
answer them?

7 A. Well, I think the evidence
8 in the literature is to the contrary. I would be
9 surprised if anybody ever demonstrated that because
10 there is evidence that seizures can be associated
with it, although, certainly not uniformly.

11 Q. Now, Doctor, the last area
12 is Mr. Olah this morning asked you about the
13 Pacsai sample, about the Pacsai case, and he asked
14 you whether your best view was that the administration
15 of digoxin in that case would have been administered
16 intravenously or orally and he pointed out to you
17 that the other day you had indicated a preference
for oral administration.

18 I would ask you, Doctor, can you say
19 with any degree of confidence whether it was oral
20 or intravenous or can you prefer one to the other?

21 A. I think my vasculating back
22 and forth illustrates my lack of confidence in
23 trying to assign a route of administration to this
24 case and I suppose I should leave it there.
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MS. CECCHETTO: Thank you, Doctor.

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THE COMMISSIONER: Thank you.

4

Mr. Young?

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MR. YOUNG: I have no questions,

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Mr. Commissioner.

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THE COMMISSIONER: All right, thank
you. Miss Cronk?

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MS. CRONK: Thank you, sir.

9

RE-DIRECT EXAMINATION BY MS. CRONK:

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Q. Dr. Kauffman, I will try to

11

be as brief as possible under the circumstances.

12

A. You are very kind.

13

Q. Not yet I'm not, but I will

14

do my best. Just a few areas that I would like to
cover with you if I could. Could we deal first
with the case of Stephanie Lombardo and Jesse
Belanger.

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You may recall in a discussion that

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must now appear to be eons ago with Mr. Scott that

19

your attention was drawn to certain portions of

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Mr. Cimbura's evidence concerning the mass spectrometry
tests which had been performed on the exhumed tissues
of both of those children. Do you recall in broad
terms that discussion?

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A. I recall that discussion, yes.

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3 Q. And your attention was drawn
4 to certain specific portions of Mr. Cimbura's
5 evidence regarding particularly Jesse Belanger and
6 further discussion ensued and you were then asked this
7 question, and I would like to refresh your memory if
8 I may. It is found, Mr. Commissioner, at Volume 73,
9 page 6184. The discussion with respect to both
10 children starts at 6184. The question with which
11 I am particularly interested is found at page 6189
12 and it reads as follows, Doctor, at the very bottom
13 of the page if you have the transcript there:

12 "Q. Well, if you were told that
13 in the cases of Belanger and Lombardo --"

14 A. I'm sorry which page?

15 Q. I'm sorry, sir, page 6189.

16 A. All right.

17 Q. The very bottom of the page,
18 last question, Doctor.

19 A. Yes.

20 Q. It reads:

21 "Q. Well, if you were told that
22 in the cases of Belanger and Lombardo
23 the mass spectrometry that was done
24 did not, to a significant degree,
25 illustrate the presence of digoxin



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"in the body, in the exhumed tissues
of those two babies, would that lead
you to qualify your assumption in this
case?"



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And your answer was:

"A. Yes, I think you have given me a hypothetical question and I will give you a hypothetical answer.

Q. Yes.

A. If I was assured that mass spectrometry had failed to demonstrate the presence of digoxin in the tissues I would have a greatly decreased confidence that it was there.

Q. Yes. Can you tell me, maybe it is just an unfair question, what would that do to your CDC list where you got them at 4 and 3 respectively?

A. I would have to look at it but I suspect, answering you without a great deal of forethought, that is my assessment of the highest probability was that there was no digoxin in their tissues, they would probably be reduced from ..."

And then I suggest to you there is something missing from the transcript. The rating on Lombardo was a 4, and the rating that you gave Belanger originally



Kauffman, re.dr.
(Cronk)

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was a 3:

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"...to a 2 or a 1.

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Q. Thank you.

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A. Depending on their clinical
status. You see, I was asked to look
at the paper from a pharmacological
point of view."

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Do you recall that discussion, Dr.

9

Kauffman?

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A. Yes.

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Q. In the case of Belanger, the
passages read to you by Mr. Scott from Cimbura's
testimony were those in which Mr. Cimbura first
described results of the mass spectrometry test
that had been done on that child's exhumed tissues.
Secondly, indicated that after discussion by Mr.
Cimbura with the mass spectrometrists involved, and
after, based on his own review of the test results
that Mr. Cimbura had reached a conclusion that
the mass spectrometry results were inconclusive.
Do you recall that, Doctor?

20

A. Yes, I recall that.

21

22

Q. We are talking now about
Belanger.

23

A. Right.

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2 Q. What was not read to you, sir,
3 at the time, was Mr. Cimbura's further evidence
4 concerning tests done on Belanger's exhumed
5 tissues and I would like to take a moment to read
6 that to you. It is found, Mr. Commissioner, at
7 Volume 52, page 1713, and this is during the cross-
8 examination conducted by Mr. Brown, and starting
9 at page 1713 the question is, I'm sorry, to help
10 you, Doctor, because I know you do not have this
11 transcript, Mr. Cimbura had just indicated that
12 based on the mass spectrometry results he felt
13 them to be inconclusive:

13 "MR. BROWN: Q. Therefore the results
14 that you would place more confidence
15 in would be the results of your own
16 analysis using the HPLC and the RIA?

16 A. Well, because of that of course
17 there was a concern in my mind and
18 we have devised another HPLC
19 procedure.

20 Q. For the Belanger tissues?

21 A. That's right.

22 Q. And the results of procedure,
23 are those results reported, are they
24 recorded in your report of September
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"29th?

A. Well, the conclusion is that the substance was digoxin.

Q. So, if I can simply be clear on the procedure. You initially subjected the Belanger test to the -

A. To the regular HPLC.

Q. ...to the regular HPLC. You then subjected them to the mass spectrometry. Those results were not sufficiently certain to allow you to draw a conclusion and you subsequently subjected the Belanger tissue to another HPLC extraction?

A. A different - well, HPLC analysis using a different column and a different mode of liquid chromatography called so - called normal mode of chromatography.

Q. And after you had extracted a substance you subjected that substance to the RIA assay?

A. That's right.

Q. And the results of that final test then are recorded on page 3



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"of your report of September 29th?..."

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And the discussion continues and I don't believe it

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is germane. Then Mr. Cimbura adds this:

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"A. There was one more test in

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addition to what I have described.

7

We obtained another set of regions

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for RIA which would have a different

9

antibody from a different manufacturer

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and we have used that also in the analyses

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of the liver from the child Belanger

12

and that also gave positive results

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and my conclusion at the end of all

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of this work was that I was reason-

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ably satisfied that the substance is

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digoxin, that's right."

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Dr. Kauffman, in light of that evidence

18

and bearing in mind what Mr. Cimbura said concerning

19

the results from the mass spectrometry tests and

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the further HPLC and RIA tests which were done

21

on the Belanger tissues, is the confidence which

22

you originally placed in Mr. Cimbura's results in

23

this case affected in any way?

24

A. You mean when I initially

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did my report?

Q. That's right.



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2 A. No, I think based on what
3 you have just told me that I would have at least
4 the same degree of confidence that I had when I
5 initially issued my report.

6 I think the fact that the separation
7 from the tissue extract was done on two very different
8 kinds of columns, markedly reduces the probability
9 that a co-eluding substance would migrate with
10 the digoxin in both systems, that is the standard
11 technique that is used to get away from that
12 problem. The fact you used two different antibodies
13 to detect the digoxin which was eluded from the
14 different columns strengthens it. So I think that
15 I would have a great deal of confidence in the
16 results if all of these methods are showing the
17 same thing. As I think I said earlier the mass
18 spectrometry is a powerful tool but it is not
19 infallible, and in a very complex matrix like
20 tissue sometimes it is very difficult to get a
21 clean enough mass spectrum to be definitive.

22 So I think taking that into con-
23 sideration and looking at the testimony that you
24 have just read me, I would have a great deal of
25 confidence in the results.

Q. Doctor, you will recall that



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Kauffman, re.dr.
(Cronk)

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2 you originally rated the Belanger child for the
3 CDC group with a probability rating of 3. Having
4 regard to the confidence that you have told us
5 you would place in light of Mr. Cimbura's evidence
6 on his results, are you inclined in any way to
change that assessment?

7 A. No.

8 Q. Could we deal in the same
9 way with the case of Stephanie Lombardo because I
10 was left in some confusion on that aspect of the
11 matter, Doctor.

12 You will recall that Mr. Scott
13 drew your attention again to the mass spectrometry
14 tests which had been conducted on that child. To
15 assist you, Mr. Cimbura testified that mass spectrometry
16 and gas chromatography tests were conducted, as
17 were RIA and HPLC, and - I am sorry, it was RIA
18 and then HPLC/RIA tests, and that those were
19 conducted on the fluid and the heart tissues specimens
20 from this child. He was then asked, this is Mr.
21 Cimbura, during cross-examination, this question
22 by Mr. Brown. Mr. Commissioner, this evidence is
23 found at Volume 52, page 1709:

24 "Q. I recall this morning, Mr.

25 Cimbura - and, again, perhaps if I



Kauffman, re.dr.
(Cronk)

1
2 "go to that, when you first appeared
3 before the Inquiry you were asked
4 a question I believe on the Lombardo
5 child, although the name "Lombardo"
6 is not used. You indicated that the
7 results that you obtained from the mass
8 spectrometry tests were not included
9 in your official reports; is that
correct?

10 A. What I meant to imply is that
11 the conclusion from that test was not
12 included - I am sorry, the conclusion
13 from the test was included in my
14 report saying that the substance was
15 digoxin. The conclusion of a mass
16 spectrometry test is supportive
17 information to the other tests that
18 the substance that is being analysed
19 is digoxin. So, I have not specified
20 the three different tests, that's
21 right, but I concluded that the
22 substance was digoxin and so you
23 viewed the mass spectrometry results
24 as a confirmation of a positive finding
25 in this instance.



Kauffman, re.dr.
(Cronk)

1

2

"Q. In the Lombardo tissue?

3

A. That's right, sir."

4

In light of that evidence, Dr. Kauffman,

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by Mr. Cimbura, is there in your opinion reason to
doubt that digoxin was in fact found to be present
in the exhumed tissues of that child?

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A. No, I don't think so.

8

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Q. Do I have it correctly,
Doctor, that if digoxin was present as indicated
by Mr. Cimbura in her exhumed tissues, you would
rank this child as indeed you did in the CDC group
with a probability rating of 4 in terms of digoxin
involvement?

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A. I see no reason to change
my ranking.

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Q. One other matter concerning
the Lombardo child, Doctor. You may recall that
during the course of cross-examination by another
counsel, it was suggested to you and indeed as I
recall it this came up during your evidence in
chief, that the child's shunt may have occluded,
and that if it was occluded that it would explain
the child dying when she did and in the manner that
she did.

23

You I believe indicated, or at least

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Kauffman, re.dr.
(Cronk)

10
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2 expressed your agreement with that, that indeed if
3 the shunt had occluded that would explain the way
4 and the manner in which the child died, do you recall
5 that?

6 A. It could have explained it if
7 it did occlude, yes, I remember.

8 Q. Also as I recall your evidence
9 and this is found, if you would like to look at it,
10 Dr. Kauffman, but I do not believe it will be
11 necessary, it is found at Volume 73, page 6073. I
believe you indicated.

12 A. I am sorry, which page?

13 Q. I am sorry, page 6073, Volume
14 73, this is during the course of discussion with
15 Mr. Strathy I drew your attention to the fact that
16 in the medical records of Stephanie Lombardo there
17 is a note indicating that a resident shortly before
18 her death was unable to detect the sound of a murmur,
do you recall that?

19 A. Yes, I remember that.

20 Q. And it was suggested to you,
21 and I believe you agreed, that the absence of a
22 murmur, or at least the inability to detect a
23 murmur that close to the child's death was consistent
24 with the hypothesis that the shunt had in fact
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Kauffman, re.dr.
(Cronk)

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occluded; do you recall that?

A. It is consistent with it,
yes.

Q. By the same token, Doctor,
would I be correct in suggesting to you that although
you would expect to hear a murmur, because of the
child's inherent arrhythmia and reduced cardiac
output of which you spoke, that you might not in
fact hear a murmur although the shunt could still
be open or patent?

A. It would be possible for the
shunt to be anatomically patent and for you not
to hear a murmur if the cardiac output was
adequately decreased at that point in time. A
murmur is simply vibrations due to turbulence
of the blood being forced through the vessel,
and if the flow and the pressure driving the flow
is low enough at that point in time that you are
listening you may not hear a murmur. So that is
another possible explanation for not hearing a
murmur at that point in time.

Q. Do I have it correctly then,
Doctor, that the inability to hear a murmur at
that point in time is not determinate in one way
or the other as to whether the shunt had in fact
occluded?



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A. In my mind it is not conclusive.

THE COMMISSIONER: That one way or another concerns me, it does concern you.

THE WITNESS: Yes, you can't ignore it. If you hear the murmur you can be sure the shunt is open. If you don't hear the murmur and the baby is in shock, or has markedly reduced cardiac output you don't know definitively whether the shunt has occluded and the baby's problem is due to that, or there is something else causing the decreased cardiac output and you don't hear the murmur because the cardiac output is not adequate to produce the murmur.

Q. Dr. Kauffman, I would like you to assume for the moment that the shunt of Stephanie Lombardo had in fact occluded, and perhaps it is a question of the obvious. I take it we can agree that an occluded shunt without more would not of course explain the presence of digoxin in the exhumed tissues from that child?

A. That is true.

Q. And I would like to draw your attention specifically to the concentrations of digoxin which was found in the exhumed tissues of



Kauffman, re.dr.
(Cronk)

1
2 Stephanie Lombardo, and you will recall you were
3 asked to look at this previously. They are found
4 in Mr. Cimbura's report dated March 25th, 1982,
5 Dr. Kauffman. The level in the chest fluid tested
6 on mass spectrometry that is at page 2, Mr.
7 Commissioner, Exhibit 95C, it is the March 25th
8 report, sir.

9 THE COMMISSIONER: I am going to
10 make another suggestion and perhaps it doesn't have
11 to be available until the new year, but an index
12 for 95 generally would be nice, I would be grateful
13 and I think everybody would be grateful if we had
14 one.

15 MS. CRONK: Would you like that to
16 go on your Christmas list?

17 THE COMMISSIONER: Yes, on my
18 Christmas list.

19 MS. CRONK: Q. For the moment, sir,
20 just to help you it is 95C and it is at page 2.

21 THE COMMISSIONER: Thank you.

22 Q. Dr. Kauffman, I would ask
23 you without my going through each individual reading
24 with you to review the readings, the digoxin
25 concentrations that Mr. Cimbura did report.

I suggest to you that they are



14 1
2 uniformly high in each of the tissue specimens that
3 were tested; would you agree or disagree with that?

4 A. I think in general that is true.
5 I had to take into consideration that they were
6 from exhumed tissues.

7 Q. Indeed.

8 A. Given that they seemed to be
9 somewhat high and were present and it was present
10 in all the tissues that were examined in relatively
11 high concentrations.

12 Q. If we look at the sample,
13 the types of specimens involved, Doctor, there
14 were high digoxin concentrations found in a great
15 number of different tissue specimens, is that
16 correct?

17 A. That is what I meant, yes.

18 Q. You have told us previously,
19 Doctor, at length, that there can be in your
20 judgment no reliance placed on the numbers them-
21 selves, the quantitative levels supported by Mr.
22 Cimbura on exhumed tissues. But having regards to
23 the results which were recorded, the number of
24 tissue specimens that were in fact assayed, do
25 you attach any significance to the fact that
comparatively speaking these levels were all



consistently high in a wide variety of tissue specimens?

A. Do I attach any significance to that?

Q. Yes.

A. Well to the extent that enough digoxin had to be given to this baby to produce concentrations in these ranges, and that it had to be given some time prior to death, at least sufficient time for general tissue distribution to take place, I think the latter is probably the most significant.

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Q Did the levels themselves and the specimens from which they were obtained assist you in any way in setting this case apart, for example, from that of Jesse Belanger or Jordan Hines, or were they in your own mind essentially the same situations?

A Well, to the extent that the levels appeared to be higher and I had data in many more tissues than in the other two patients, it gave me somewhat more confidence that digoxin was really present and was distributed.

In addition, the description of the clinical course of this baby's death I think led me to contribute it to my putting her in a higher category also.

Q Well, I was concerned about that, Dr. Kauffman, because I had understood you to say this morning, and perhaps I misheard you, when you were speaking to Mr. Olah with respect to these levels that you took the levels into account very little, if any; those were your words as I wrote them down.

A No, I was referring then specifically to the contents in the stomach and the bowel.



EE.2

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Q. I see.

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A. Not to the tissue concentrations.

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He asked me specifically about the amounts -- not

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concentrations, but the amounts in the stomach and

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the small bowel, and I said those numbers were not

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of great consequence in making a determination in

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this patient, but I was not referring at that point

in time to the tissue concentrations.

9

Q. I take it from what you have

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said that the tissue concentrations did indeed have

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some relevance for you?

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A. Yes, they certainly did.

13

Q. Doctor, I trust you have Mr.

14

Cimbura's reports in front of you. Could I ask you

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to turn as well, if you would, please, to the report

dated April 6th, 1982. That is Exhibit 95D.

16

A. I confess I did not have it

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directly in front of me but I will dig it out here.

18

Which date?

19

Q. April the 6th, 1982, Doctor,

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page 1 of that report.

21

A. Okay, page 1, I have it.

22

Q. You will recall, Doctor, I

believe it was during the cross-examination of Mr.

23

Scott, but I may be in error as to which counsel was

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2 involved, that your attention was drawn to the
3 findings of the concentrations of methyl and ethyl
4 alcohol which were found by Mr. Cimbura in a number
5 of specimens, specifically there were three specimens
6 from Justin Cook tested, in two of them, T-24 and T-27,
7 both of which were blood specimens, both methyl and
8 ethyl alcohol were found, ethyl alcohol in higher
9 quantities; similarly, a blood specimen from Pacsai
10 and a blood specimen from Manojlovich were tested,
11 and once again, both methyl and ethyl alcohol were
12 found, the latter in higher concentrations than the
former.

13 Doctor, do you attach any significance
14 to the findings of methyl and ethyl alcohol concen-
15 trations in these blood specimens?

16 A. I do not know how to interpret --
17 what to make of these. I cannot really explain the
18 combination of ethyl and methyl alcohol together as
19 resulting from an injection of a drug containing
20 ethyl alcohol as a preservative or as a diluent
21 because I would not expect the methyl alcohol to be
there. So I cannot accept that.

22 Methyl and ethyl alcohol are common
23 re-agents for solvents that are present in laboratories,
24 so I suppose that there is a potential for contamination,
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EE.4

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2 but I do not know enough about how these samples
3 were obtained and handled, the details of their
4 handling, to know whether or not it would have been
5 possible for the sample to become contaminated at
6 some point with these products. I also do not know
7 enough about the assays that were used to measure the
8 alcohols to know what interferences those particular
9 assays were subject to, so I really cannot respond
10 to that.

11 The other thing I thought about was
12 that ethyl alcohol and methyl alcohol are combined
13 sometimes in a 70 per cent ethyl alcohol solution with
14 a little bit of methanol added for use as a skin
15 cleanser before doing vena punctures, and that
16 preparation would give you the general ratio that is
17 described here. But I do not understand why this
18 product would have been used, particularly in
19 obtaining post mortem specimens, and even if it was
20 used, it is hard to understand how just cleansing
21 the skin would have resulted in this degree of
22 contamination of the specimen.

23 So I really do not have any good explanation
24 for these. I do not think that the babies
25 had this much alcohol in their bodies at the time
they died because had they, they would have died a much



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different kind of death and would have had other symptoms. So I suspect they are artefacts; that is the only way I can explain it, but I do not have any logical explanation as to how the artefact occurred.

Q. Well, Doctor, I am interested in two features, at least, to what you have said. We know that some of the specimens that were tested were in fact post mortem blood specimens. For example, in the case of Justin Cook, T-27 was a post mortem blood specimen drawn at 6 a.m. on the morning of the child's death.

Now, in those situations where the blood specimen is drawn directly at autopsy from the inferior vena cava, and we know that some of these post mortem blood specimens were, I take it you can eliminate the possibility that the skin may have been swatched for the purposes of cleansing the surface before the tissue was taken? It does not apply?

A. No, I do not think that that -- I doubt if it even applies in ante mortem samples because, as I said, it is hard for me to conceive of how even cleansing the skin would produce enough contamination to produce these concentrations in a sample.



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Q. Thank you. Doctor, secondly, you indicated that were these children to have had high concentrations of either methyl or ethyl alcohol in their bodies at the time of death you would have expected them to have died in a different way with different symptoms; did I hear you correctly?

A. Yes.

Q. Are there, in fact, specific symptoms of, for example, methyl alcohol intoxication or ethyl alcohol intoxication?

A. Well, both of the alcohols would produce acutely central nervous system depression and respiratory depression certainly in the concentrations of ethyl alcohol that are suggested here. What I would expect to see is a baby who shortly after receiving it, alcohol in this kind of dose, to have marked central nervous system depression, respiratory depression and in high enough doses actually, cardiovascular depression, but a different kind of picture than what is described in these particular babies.

Q. Did any of the babies whose cases you reviewed, were there recorded in their medical records symptoms which, in your view, are suggestive or consistent with methyl or ethyl alcohol



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intoxication at the time of death?

A. No, I do not think so .

Q. Doctor, could we turn now, if you would, please, to the case of Kristin Inwood briefly, and one matter that has arisen with respect to that child. At autopsy, the findings with respect to Kristin Inwood included evidence of sub-endocardial and myocardial necrosis in the left ventricle of the heart, and as well, evidence of necrosis in the capillary muscle. I would ask you to accept that from me. That is found in the autopsy report filed before the Commission for Kristin Inwood.

It has been suggested in evidence, Doctor, that given those autopsy findings and that evidence evident at autopsy, one cannot rule out the possibility that the dying tissue in the heart contributed significantly to an elevated blood level in that child prior to death, either from the maintenance digoxin therapy which she was on prior to death or indeed, from the accidental dose which we know she received the day before her death. In your opinion, Doctor, can that phenomena occur, that is, can tissue death during life result in elevated digoxin levels ante mortem?

A. Well, as I have said previously,



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it is a hypothesis I developed to try to explain
the situation with the -- the baby's name escapes me?

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Q Gary Murphy.

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A Gary Murphy. I do not know of
objective studies that have documented whether or not
that occurs. It is based on an understanding of the
factors that may influence binding of digoxin in
tissues, so I cannot say it does not occur. I have
to say that it could occur, I think.

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Q Well, in this case, Doctor, with
the evidence that was available after autopsy, could
that phenomena, in your view, account for the post
mortem serum level obtained in Kristin Inwood, and
as well, the concentrations of digoxin found in her
various tissues, in your judgment?

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A Well, I do not think so. I
have several problems with that. One is that the
serum concentration ante mortem, I think, was
something around 2 within --

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Q 2.6.

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A -- 12 hours before the baby's
death, so it certainly was not occurring at that point.
The other thing, I have not looked at the autopsy
report recently, but as I recall, these findings
appeared to be somewhat recent findings. There was



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not evidence of longstanding scarring and repair
and recurrent damage and repair.

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My recollection is that it suggested
to me more recent damage and more acute damage, and
so with a combination of having a documented serum
digoxin of 2.6 within hours prior to the baby's
death and then autopsy findings suggestive of acute
myocardial damage, it is hard for me to accept that
that would have had a significant effect on ante
mortem digoxin concentrations in this baby.

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Q. Well, assuming, Doctor, that
the tissue death which was evidenced at autopsy, in
fact, did occur accutely prior to death on the
assumption that it did occur or at least was in the
process of occurring while there was still circulation
ongoing in the child's body, could that process, in
your view, account for the tissue levels, for example,
that were found in Kristin Inwood?

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A. I do not think it would account
for the tissue levels. Tissue levels may not change
under those conditions. I mean, your ability to
detect any change in tissue concentrations, you
probably would not be able to detect any change in
tissue concentrations.

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What I am saying is if you accept



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that hypothesis, it would be possible to release enough digoxin from the tissue to cause a significant change in serum concentration without making a detectable change in the tissue concentration because so much digoxin is present in the tissues. So I do not think the tissue concentration either proves or negates that hypothesis.

I think that it is difficult to explain the high level in the blood that was found, if we can accept a concentration somewhere in the neighbourhood of 200 to 300 nanograms per ml., I certainly cannot explain that or even a tenth of that by tissue breakdown, the kind of tissue breakdown that is described in the heart on this baby right around the time of death. I think any change that would take place would be incorporated into the usual multiplier that we talk about that occurs post mortem.

Q Well, that is what I was getting at, Doctor, because my friend, Ms. Cecchetto, took you to the post mortem multiplier that I invited you to apply in the case of Kristin Inwood, and I suggest this to you: if in fact there was evidence of massive myocardial damage, tissue damage during life, is it possible in your view that a digoxin concentration ante mortem of 2.6 the day prior to death could be



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sufficiently elevated so as to account subsequently
for a post mortem level of 200 to 300 by this
process?

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A. I do not think so, no.

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Q. Thank you, Doctor. Doctor, you
will recall Ms. Symes took you this morning during
the course of her cross-examination generally to
the matter of medication errors and suggested to you,
if I wrote it down correctly this morning, that
medication errors do repeat; do you recall that
discussion?

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A. Yes, I remember that.

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Q. And it was suggested to you as
well, as I understood it, that the possibility of
medication error increases in periods of stress or
tension; do you recall that?

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A. Yes.

Q. I would like to relate that,
Doctor, if we can, to the 36 children with whose
deaths we are concerned or at least a fair number of
them. May I start with this question: as a general
proposition, would you expect similar types of
medication errors involving the same drug to be
repeated consistently within the same time frame;
is that something that you would regard as usual?



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A. Well, I think I have said previously, I think that the probability of that is quite low. It seems unlikely to me that an error would continue to be repeated and would be clustered only in one location in the Hospital and only in one period of time. It would tend to be clustered geographically as well as chronologically.

Q. Would it be more likely, in your view, that errors of that kind would happen randomly both as to location and time?

A. Yes, I think so.

Q. Doctor, do I have it correctly that at the time that you were preparing and delivering your first report in mid-December of 1982 to Mr. Wiley that in fact you did consider the possibility of medication error as a potential explanation for at least some of the deaths of these children?



/BM/ak

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A. I think I considered it in all of them and then had to discard it for one reason or another in most of them; but I did consider it, yes.

Q. Well, most specifically, Doctor, did you consider it in the case of Jesse Belanger, Justin Cook, Jordan Hines and Stephanie Lombardo?

A. I believe so.

Q. I would ask you to turn if you would, Doctor, to page 12 of your first reporting letter to Mr. Wiley. That is the one dated December 16, 1982. Do you have that, Doctor?

A. Yes.

Q. I direct your attention to the last two sentences of the paragraph under Miscellaneous Comments which reads:

"It seems unusual that the same medication error would occur with this frequency on the same ward during the same shift, therefore, I think there is a reasonable probability digoxin was deliberately administered to these infants."

And I take it you are referring to



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those four, Belanger, Cook, Hines, Lombardo. Do I have that correctly?

A. That is correct.

Q. And was that your conclusion at the time of signing this report with respect to the possible involvement of medication error in the death of those four children?

A. Yes, it was.

Q. Did that remain your opinion at the time that you filed your supplementary reporting letter to Mr. Wiley in January of 1983?

A. Yes, it did.

Q. Is that your opinion today, Doctor?

A. Yes, it is.

Q. Doctor, we know in addition to those four children Allana Miller died on Wards 4A/4B on March 21st, 1981 and that Kristin Inwood died on the same wards on March 13th. Miller died or at least was pronounced dead at approximately 3:27 a.m. and Inwood at approximately 3:00 a.m. If asked to do so, would you express a like opinion with respect to the likelihood of medication error with those two children as well?

A. Well, I think I have to



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3 qualify it to the extent that you have to take
4 everything else into consideration as to what was
5 going on with these babies and what supporting evidence
6 you have. I think in general that it is unlikely
7 that a medication error is going to be clustered at
8 one time of the day and one location and not be
9 occurring with some comparable random occurrence,
10 incidents of random occurrence elsewhere in the
11 Hospital.

12 Q. Does it have any significance
13 to you, Doctor, if I suggest that while six of those
14 children, that is, Belanger, Cook, Hines, Lombardo,
15 Miller and Inwood died on the same wards within the
16 early hours of the morning?

17 A. Well, I think it is something
18 that you have to take into consideration and I
19 suggest that there may very well have been a non-
20 random event taking place that made that ward uniquely
21 susceptible to this kind of phenomenon.

22 Q. Doctor, two other matters
23 very briefly. You may recall that Mr. Ortved during
24 the course of his discussion with you directed your
25 attention to this same reporting letter to Mr. Wiley,
the first reporting letter, and suggested to you
that of the 40 cases which you had reviewed, there



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were 30 in which you were unable to express any
opinion. Do you recall that discussion?

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A. Yes.

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Q. As I understood your answer,
you told him that in the 30 of the 40 cases which
you had reviewed you didn't have enough information
to really express an opinion. Do I have that
correctly?

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A. I think that is in general
correct, yes.

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Q. Doctor, could I ask you to
refer to page 1 of that reporting letter if you would,
please. Mr. Ortved, and this is found at Volume 74,
page 6293 suggested further that in those 30 cases
there was no objective evidence of digoxin toxicity.
Do you recall that?

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A. Yes, I remember that.

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Q. And your answer, as the
transcript records it, is that you thought that was
a fair representation of the wording of your report.
I would like you to refer if you would, Doctor, please
to the first paragraph on the first page of your
reporting letter - I'm sorry, to the second paragraph
on the first page where you indicate:

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"The cases of 10 patients are reviewed



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"in detail below. In the remainder of the cases there was either inadequate information upon which to base a detailed review or there was no objective evidence of digoxin toxicity."

Now, as I understood it, Doctor, from my reading of your report, I took from that passage that there were two reasons which would have resulted in your not reviewing a case in any particular detail; the first was a situation where there was inadequate information available to you and the second where there was no objective evidence of digoxin toxicity. Do I have that correctly?

A. I think so, yes.

Q. And the two, would it be fair to suggest, that the two are not necessarily the same?

A. I think you are correct, yes.

Q. Is it fair then to conclude that we should not assume that in each of those 30 cases you were of the view that there was no objective evidence of digoxin toxicity?

A. No; I think either or both of those criteria applied to those cases that I didn't do detailed reviews on.



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Q. Doctor, you will recall that your attention was drawn this morning very briefly by my friend Mr. Brown to the case of Antonio Velasquez and he quite properly pointed out that that case had not been dealt with at length in your evidence in chief. As I understood you this morning you indicated that in your judgment there was, it was highly unlikely that Naloxone could produce what I thought you described as a sudden catastrophic event associated with death. Did I understand that correctly?

A. It sounds like what I remembered I used.

Q. It is not my language I assure you.

A. Right.

Q. Doctor, I take it that you are aware that the cardiologists from the Hospital for Sick Children who testified before the Commissioner, most notably Dr. Rowe and Dr. Freedom, have expressed the view that they felt in retrospect that this child's death was likely attributable to an idiosyncratic reaction to the drug Naloxone. Were you aware of that?

A. I wasn't aware of that, no.



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Q. All right. Well, Doctor, to help you with that, I take it that the chart of Antonio Velasquez was one of those which you reviewed in ranking or rating these various children for the purposes of the CDC group and as well for Mr. Wiley?

A. That is correct.

Q. All right. Doctor, what is your view, and perhaps it is the same thing that you were saying this morning, but to be sure we are clear, what is your view as to the likelihood of Antonio Velasquez' death being attributable to an idiosyncratic reaction to the drug Naloxone given the conditions and the timing under which that drug were administered to the child prior to his death?

A. Well, I think it is unlikely, not because of the timing but because it is something that to my knowledge has never been reported in the past. Now, that doesn't say it can never occur but from my knowledge of this drug and the way it has behaved in other patients even in large overdose, I would not expect it to cause this kind of problem.

Q. Doctor, you rated Antonio Velasquez with a 1 on your probability rating scale for the CDC group. Would I correctly conclude, having regard to the facts of the medical record



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2 concerning Antonio Velasquez that he necessarily
3 received that rating because there was no digoxin
4 data available to you for your review in terms of
5 ante mortem levels or post mortem toxicology informa-
6 tion?

7 A. I don't remember specifically
8 without reviewing the record.

9 Q. All right, Doctor. Well,
10 to help you with that, two things. Would you turn
11 first if you would please to your letter to Dr. Smith
12 dated December 14, 1982. That, Mr. Commissioner,
13 is at Tab 1 of the bound CDC group materials, it is
page 3 of the letter.

14 A. Which page?

15 Q. Page 3 where your criteria
16 are set out.

17 A. Right.

18 Q. To help you, Dr. Kauffman,
19 our information is that Antonio Velasquez received
20 a dose of digoxin at the Hospital for Sick Children
21 of .03 milligrams orally on August 20th and that
22 it was then discontinued. It is my understanding
23 that no digoxin level was taken during his life and
24 of course there is no toxicology data available. I
25 ask you to accept that from me, I'm sure someone will



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2 correct me if I'm wrong.

3 A. Right.

4 Q. Having regard to the criteria
5 which you set out under your rating number 1 group
6 I would ask you to look at them. Do I have it
7 correctly that the only possible rating that child
8 could have received by definition under your groupings
9 was that of rating 1 or because there was no
10 appropriate digoxin information available to you to
11 assess the case?

12 A. That is correct and I assume
13 he was receiving an appropriate dose and that would
14 fit the criterion also.

15 Q. All right. Does the fact,
16 Doctor, that there was no ante mortem digoxin level
17 available on this child nor any post mortem informa-
18 tion, did those two facts preclude you from forming
19 any opinion as to the likely involvement of digoxin
20 intoxication in this case?

21 A. Well, to the extent that I
22 had no data one way or the other.

23 Q. All right.

24 A. As I pointed out, infants
25 for whom I had no digoxin data I included in the
category 1.



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3 Q. Well, Doctor, are we left
4 then in this situation. If you are reluctant to
5 accept as the explanation for this child's death an
6 idiosyncratic reaction to Naloxone yet are unable
7 due to lack of information to formulate a view as
8 to the possible involvement of digoxin, is there
9 in your own mind any reasonable explanation for this
10 child's death which on the evidence before you you
11 are prepared to accept?

12 A. I think before I answer that
13 intelligently I would have to review the chart again
14 because I don't remember the details on this baby's
15 death. But I suspect that because of the way I
16 ranked him I would attribute his death to some other
17 cause. You must understand that when I was ranking
18 these cases, trying to rank them or place a rating
19 on them with respect to a probability judgment as
20 to the probability of digoxin being related to their
21 death, I was doing it primarily in the context of
22 the pharmacologic data available because I knew
23 that the clinical data were being evaluated
24 independently of me. So, I used the clinical
25 data secondarily as supporting information but
when I did not have pharmacological data I did not
give them a high ranking, assuming that the cardiologist



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FF11 and the pathologist might or might not disagree with
3 my ranking because I was doing it on different
4 grounds than what they were.

5 Q. Well, I understand that,
6 Doctor. My question really is this. Are you in a
7 position to assist the Commissioner, and you may
8 well not be, but are you in a position to assist
9 the Commissioner as to what you consider to be
10 the likely explanation for this child's death?

11 A. I would have to look at the
12 chart again to be of help to you because I frankly
13 don't remember the details.

14 Q. Sir, I have one matter left.
15 It will take approximately 5 minutes, I'm in your
16 hands, 5 to 10 minutes.

17 THE COMMISSIONER: I will take a
18 vote. I know the answer will be to proceed, but I
19 am going to take just your view, if you would like
20 to take a break now or would you like to finish,
21 assuming that Miss Cronk is telling the truth,
22 which she does sometimes. Would you like to proceed
23 or would you like to take a break?

24 THE WITNESS: A break is fine with
25 me if you want to. It is no problem for me either
way.



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THE COMMISSIONER: Well, I'm pretty sure that the general view will be to proceed and there will be a great deal of hissing or booing if you go beyond the 5 minutes.

MS. CRONK: Q. Dr. Kauffman, you will recall that your attention was drawn in the case of Kevin Pacsai to the fact that upon that child's admission to the Intensive Care Unit on the morning of his death he re-established for a period of time sinus rhythm. Do you recall that?

A. Yes, I remember that.

Q. That came up, as I recall it, in your discussion with Mr. Shinehoft and it may well have come up in your discussion with Mr. Scott. If I understood your evidence correctly, and please correct me if I am wrong, it was your view that that fact, that is, the re-establishment of sinus rhythm did not mitigate against or reduce the possibility that digoxin intoxication had contributed to his death. Do I have that correctly?

A. I think that is correct.

Q. You have produced to me, Doctor, three articles which you have told me bear on this issue and that you would like to refer to before you complete your evidence before this



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Commission. The first article is entitled "Massive Digoxin Intoxication in Childhood" by - I think I'm mispronouncing it, who are the authors?

A. I'm not sure I can pronounce it either.

Q. Stopfkuchen.

A. Yes, Stopfkuchen.

Q. And that is published in the Intensive Care Medicine Magazine, the 1978 publication, correct?

A. Volume 4.

Q. Right.

THE COMMISSIONER: What number is that?

THE REGISTRAR: 297.

THE COMMISSIONER: Exhibit 297.

MS. CRONK: That is the first one, sir, and I'm going to identify the other two.

THE COMMISSIONER: Yes, all right.

MS. CRONK: Q. You have produced for me as well, Doctor, an article entitled "Digitalis Toxicity in Infants and Children" by Lee published in the Pediatrician Journal, I believe that is 1973.

A. It is Volume 2, 1973.

Q. Right. The final article that



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3 you have produced to me is entitled "Suicidal and
4 Accidental Digoxin Ingestion - Report of Five Cases
5 with Serum Digoxin Level Correlations" by Smith and
6 Willerson, and that was published in July, 1971.

7 Do I have that correctly?

8 A. I believe so, yes.

9 Q. I would ask, Mr. Commissioner,
10 that they be marked accordingly.

11 THE COMMISSIONER: The first one
12 "Digitalis Toxicity in Infants and Children" will be
13 298 and the "Suicidal and Accidental Digoxin Ingestion -
14 is 299.

15 ---EXHIBIT NO. 297: Article entitled "Massive
16 Digoxin Intoxication in Child-
17 hood" by Stopfkuchen published
18 in Intensive Care Medicine
19 Magazine, Volume 4, 1978.

20 ---EXHIBIT NO. 298: Article entitled "Digitalis
21 Toxicity in Infants and Children"
22 by Lee published in Pediatrician
23 Journal, Volume 2, 1973.

24 ---EXHIBIT NO. 299: Article entitled "Suicidal and
25 Accidental Digoxin Ingestion -
Report of Five Cases with Serum
Digoxin Level Correlations" by
Smith and Willerson, published
in July 1971.

MS. CRONK: Q. Doctor, can you
tell us please why you feel these articles to be
of assistance?



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A. They contain case reports of
patients who have been documented to be suffering
from digitalis intoxication in whom the arrhythmias
varied from time to time during the course of their
illness but included at some point in time a sinus
rhythm in addition to the dysrhythmia that occurred.



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2 I simply pulled them out to document that within
3 the complex of dysrhythmias that have been described
4 during the course of severe digitalis intoxication
5 that a sinus rhythm can occur for a short period of
6 time, and then the other dysrhythmias can supervene,
7 that is the only point of these.

8 Q Well, by way of illustration
9 only, Doctor, can we look at the third of the three
10 articles entitled "Suicidal and Accidental Digoxin
11 Ingestion", this as I understand it is a report of
12 five independent cases. I would ask you to turn
13 first if you would to the first case setting out
14 on page 30 and if I read the article correctly,
15 Doctor, this involved the case of a two-year old
16 boy who had ingested a number of digoxin tablets.
17 On admission to the hospital an ECG was taken and it
18 showed slight sinus arrhythmia and within four hours
19 after admission the child developed intermittent
20 sino-atrial pauses, or more likely as the author
suggests SA exit block was observed with probable
atrioventricular junctional escape beats.

21 Reading on in the article:

22 "Atropine in small doses immediately

23 ... ",

24 and the child immediately was restored to normal sinus
25



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rhythm, am I reading that correctly?

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A. That is correct.

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Q. As I understand it ultimately
some 28 hours after the ingestion of the digoxin
tablets the child in fact had reverted with some
consistency to normal sinus rhythm?

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A. That is correct.

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MS. CRONK: Thank you, Doctor.

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Doctor, on behalf of the Commission
and counsel and present I would like to thank you
for the time and the care that you have extended the
Commission, I know your evidence has been of great
assistance and I will sit down now, sir, before the
Commissioner decides to take away my Christmas present.
Thank you very much.

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THE WITNESS: Thank you.

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THE COMMISSIONER: Thank you very much,
Doctor. Pay no attention to what Miss Cecchetto said,
if you don't want to go home you don't have to but I
do recommend that you get away from here.

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THE WITNESS: I will, thank you.

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THE COMMISSIONER: Thank you. Until
10 o'clock tomorrow morning?

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MS. CRONK: Yes, sir.

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THE COMMISSIONER: And we will continue.

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--- Whereupon at 3:40 p.m. the hearing adjourned
until Tuesday, December 20th, 1983, at
10:00 a.m.

